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a limb at your
fingertips

IDSF

Intramedullary Diaphyseal Segmental Defect Fixation

- **Improved Rotational Stability** for Early Load Bearing
- **Intraoperative Adjustability** and Optimal Modularity
- **Nail and Spacer Sizes** for Optimal Diaphyseal Fit

OsteoBridge™
Merete® Limb Salvage Systems

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Second Generation OsteoBridge™ IDSF

The second generation of Merete's OsteoBridge™ IDSF is available for use. This brochure compares available reconstruction options and illustrates results from mechanical tests that depict improved torsional stability for a novel clamping mechanism.

Endoprosthesis options are typically selected for oncology patients of advanced age and decreased stage that require immediate mobilization and pain control. For this, current segmental defect replacement systems provide 1) enhanced immediate and long-term stability postoperatively, 2) the potential to irradiate safely while providing continuous intercalary support and 3) modularity for varying defect locations and sizes. A novel clamping mechanism was developed and incorporated in IDSF's intercalary segment to secure the spacer/nail interface against increased loads. Previously needed reduction-bushings (first-generation) were removed and equidistant grooves were introduced on a smooth, sand-blasted cylindrical nail interface to improve the systems press-fit. This feature allows intraoperative adjustments after the nails are fixated in the proximal and distal fragments, prevents distraction or over-extension before the components are engaged and most importantly, has the potential to reduce structural failures through elevated torsional stability. Additionally, Merete® preserved the systems modularity for an extended range of defect sizes (40 to 140 mm) and provides nail diameters for various intramedullary conditions.

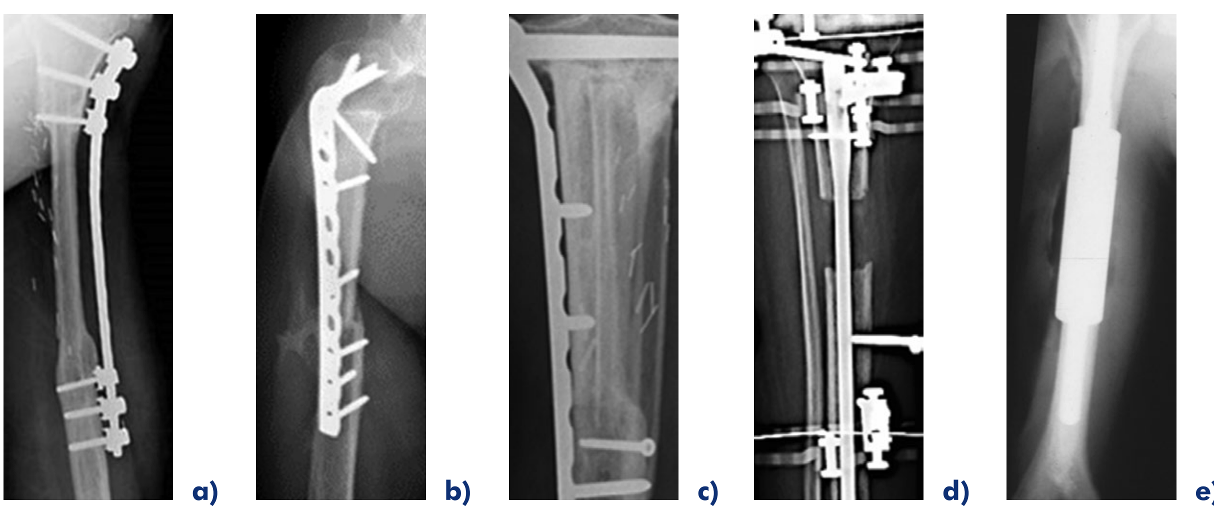


Figure 1. Reconstruction Options for Joint Sparing Intercalary Resections. Biologic option including a) autograft, b) allograft, c) composites and d) bone transport or, alternatively, e) endoproshesis (left to right).

Background

Segmental defects in diaphyseal bone of the femur, tibia and humerus are often the result of primary malignant tumors, secondary metastasis.

Intercalary resections allow joint sparing interventions with fast postoperative mobilization and high functional scores through the preservation of the physes. Timely definitive fixation and stabilization in this patient population is essential so that further systemic chemotherapy and local radiotherapy can be done. Thus, implants that provide immediate stable fixation and maximal pain relief with minimal complications are needed. Several biological and endoprosthesis solutions are clinically available, though a variety of factors need to be taken into consideration before an approach is selected.

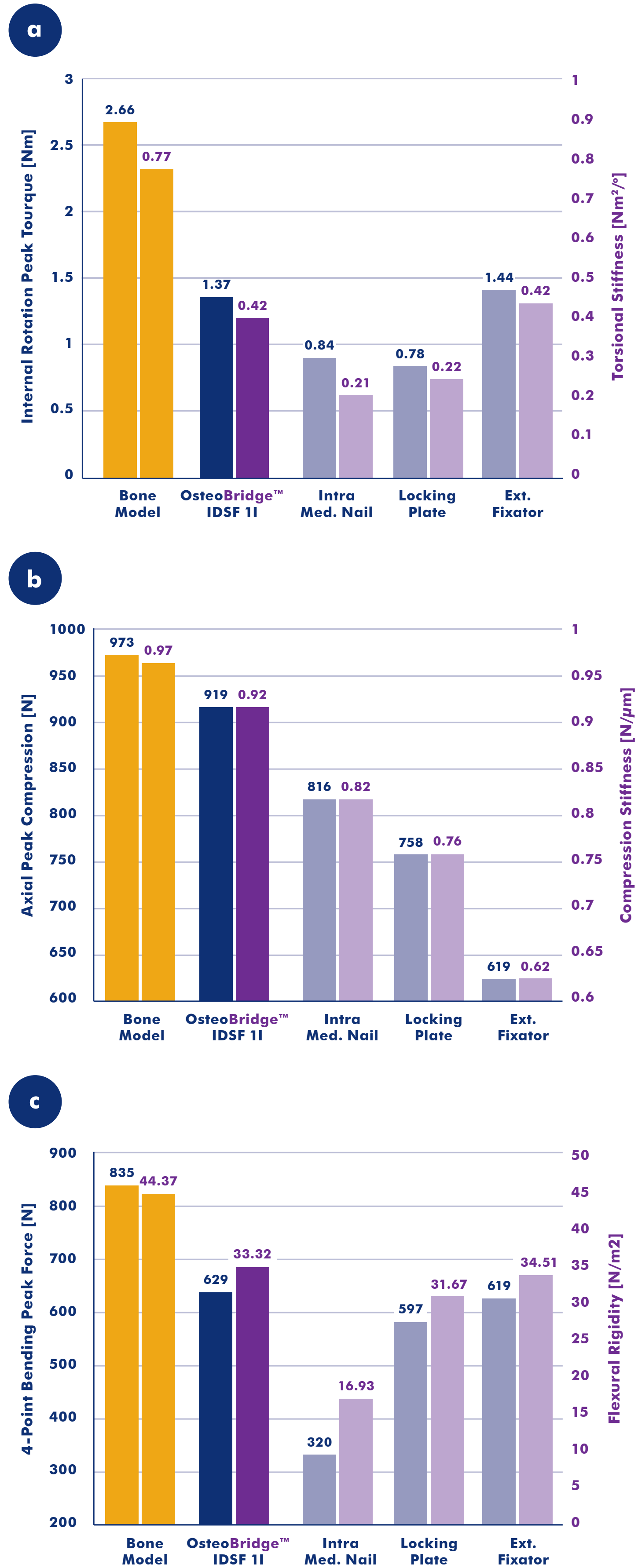
Biologic options available for reconstruction include autografts, allografts, composite reconstructions and bone transport (Figure 1). With these options the healing phase may be prolonged [1]. Delay in weight bearing may lead to additional complications which are devastating in patients with limited life expectancies. Vascularized autografts are successfully applied in patients with sufficient bone quality but, transplant sizes are often limited, provide inadequate fixation for sizable lesions and require several years before they are fully weight bearing. Allografts are available in larger sizes and allow soft-tissue attachment, yet an extended off-loaded period is also needed until graft union is achieved. Non-negligible complications such breakage, infection and non-unions are often the consequence [2,3]. Bone transport through distraction osteogenesis is a promising alternative but the treatment is time-consuming (~90 days) due to the average defect sizes of 90 mm, combined with slow average distraction rates of 1 mm/day [4].

Endoprosthetic reconstruction allows early weight bearing, avoids cemented reconstructions and allows for postoperative radiation. Previous biomechanical studies on cemented implants show adequate stability and fixation for several prosthetic implants [5, 6]. Henry et. al. compared intramedullary nails with added cement bodies, or intercalary allografts to segmental defect replacement protheses with titanium spacers. Each implant bridged a 5 cm mid-diaphyseal resection in fresh frozen humeri. Titanium spacers showed significantly greater torsional stability (mean peak torque, 41.4 Nm) and stiffness (mean, 2.1 Nm/°) than locked intramedullary nails (mean peak torque, 23.1 Nm) (mean stiffness, 1.6 Nm/°) or allograft nail composite specimens (mean peak torque, 12.4 Nm) (mean stiffness, 0.6 Nm/°) [5]. Thus, mechanical properties of titanium body segments are favorable to other reconstruction methods. For instance, the first generation OsteoBridge™ Intramedullary Diaphyseal Segmental Defect Fixation (IDSF) has increased compressive loads, flexural loads and torsional loads compared to locking plates and intramedullary nails (Figure 2) [6].

Generally, form-fitted junctions such as lap joints or morse tapers with linked female and male components depict elevated rotational stability compared to press-fitted segments (as in IDSF). Morse tapers made modular solution clinically available, though, prosthetic dissociations have been reported. Modern lap-joints provide better stability due to screw fixation within the junction. Both systems offer several stem-body sizes to create the prosthesis, however, each intercalary junction is assembled with the nail component before they are connected. Hence, proximal and distal nails may not be rotated relatively to each other after the cement is hardened or interlocking screws are inserted. A minimal intercalary distance is also required to incorporate and attach the parts. Thus, enlarged resections are needed that lead to shorter nails in the remaining intramedullary canal. The cemented or osseo-integrated interface with the nail is, therefore, reduced which in turn increases to risk of aseptic loosening. Furthermore, intraoperative distraction is compulsory to engage the junctions which induces neuropraxia by overextending peripheral neurons.

Segmental replacement systems with press-fitted components allow shorter body segments that do not require an enlarged resection or interoperative overextension. OsteoBridge™ IDSF nails include an 18 mm clamping area that extends past the osteotomy plane into spacer half-shells they are fixed with clamping screws. First, this allows surgeons to intraoperatively adjust the implant and rotate the fragments relative to each other with nails cemented or interlocked in the intramedullary canal. Secondly, different nail diameters may be combined depending on the intramedullary conditions proximal and distal of the resection. And thirdly, the outer spacer diameters were adapted to match the anatomical conditions in femur, tibia and humerus to avoid postoperative prominence, soft-tissue interferences and to facilitate bone overgrowth. In summary, this provides the IDSF system with extensive modularity for a wide range of defect sizes. Though, structural failures in press-fitted body segments needed to be minimized to reduce non-oncological complications and to improve immediate and long-term stability [10].

This brochure expands on current literature regarding reconstruction of large diaphyseal lesions. Additionally, it presents a novel press-fitted clamping area, biomechanical test results, and an increase in torsional stability. Merete's® approach presents a mechanically secured construct that may lead to a reduction in structural failures, preserved features such as modularity for a range of defect sizes in femur, tibia and humerus and maintained the surgical ease-of-use that allows intraoperative rotational adjustments before the spacer half-shells are press-fitted over the nail ends.



Courtesy of Sakellariou VI et. al. 2012. J of App Biomech. [6].

Figure 2: Comparing Mechanical Properties of Endoprosthesis Options. Results for a) torsional rigidity plotted with peak rotating torque, b) maximal axial compression forces with compression stiffness and c) greatest bending forces as well as flexural rigidity, illustrated for bone composite models (Sawbones Europe AB, Pacific Research Laboratories, Inc.), segmental defect replacement systems (OsteoBridge™ IDSF I, Merete Technolgies, Inc.), intramedullary nails (Polarus, Acumed), locking plates (LCP Plates, Synthes) and external fixators (LRS, Orthofix)[6].

Novel Press-Fit

A mechanical analysis of the press-fitted nail/spacer interface was performed to optimize the body segment of OsteoBridge™ IDSF for maximal rotational stability.

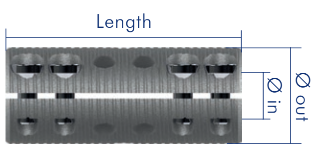
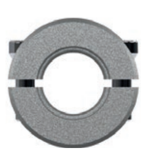
The first-generation junction used a reduction-bushing to fit nail diameters, adapted from the intramedullary canal, into each spacer. The reduction-bushing was removed in the second-generation clamping area to reduce the number of articulating surfaces and increase the nail diameters within the spacer. The nail profiles, additionally, received a sand-blasted surface with four edged grooves distributed equidistant around their circumference of the clamping area. So that an 18 mm cylindrical extension of each nail end is then press-fitted into untreated spacer half-shells by tightening eight screws to fixate the assembly.

Subsequently, first- and second-generation clamping areas were compared in torsional performance tests, conducted internally (Merete GmbH, Germany) and at an external laboratory (Rutgers New Jersey Medical School, NJ). Independently calibrated servo-hydraulic machines were used. Individual nail sizes were identified and assembled with spacers.

The assemblies were mounted in custom made fixtures that were rotated while the torque per degree was recorded. Peak torque and angle at failure were collected for femur, tibia and humerus constructs of first-, and second-generation clamping areas. Failure modes were defined as: 1) frank component failure with a negative torsional slope over less than 10° of rotation and 2) component slippage represented as a reduced rate of change in torque per 2° intervals of rotation.

All components were manufactured from titanium alloy (TiAl6V4 ELI) under batch conditions (null-series) to represent the surface and mechanical properties of the implants. In this, spacers were provided with outer diameters of that diaphysis in femur, tibia and humerus (Table 1) for optimal anatomical fit. Additionally, each nail was manufactured with outer diameters that match the inner diameter of the spacer. Spacer lengths from 40 to 70 mm were made that may potentially be paired with spacer connectors to span resections widths from 40 to 140 mm.

Table 1: OsteoBridge™ IDSF. Spacer sizes for resections from 40 to 140 mm (10 mm steps) and nail diameters (1 mm steps) for Femur, Tibia and Humerus.

Spacer Size in mm			**Bone**	**Nail** Size in mm	
Length	**Ø out**	**Ø in**		**Ø out**	**Length**
40	—	—		—	—
50	20	10	Humerus	7-10	60-130
60	25	14	Tibia	9-14	60-200
70	34	16	Femur	10-20	60-200
					

Improved Rotational Stability

Structural failures with OsteoBridge™ IDSF constructs occurred solely in femur through postoperative torsion under excessive load. The reduction of type three complications was, thus, the most clinically relevant goal in our efforts to improve the prothesis.

The press-fitted junction of Merete's implant was redesigned to provide clinicians with a novel and more stable clamping mechanism. Removing the reduction-bushing reduced the number of articulating interfaces from two (spacer/reduction-bushing and reduction-bushing/nail) to one (spacer/nail) and improved the rotational stability while modularity was preserved. The outer nail diameters matched the inner spacer diameter throughout an 18 mm cylindrical extension. The increased diameter mechanically protracted the rotational leaver in the press-fitted clamping construct while the frictional resistance was elevated through the novel surface.

The inclusion of four edged grooves provides eight cultrate boundaries within a smooth, sand-blasted clamping interface. This inhibited rotation after the clamping screws were tightened down. There were no failures observed which were associated with breakage of clamping screws, breakage of spacer or breakage of nails. The novel clamping area increased the peak torque in femur constructs from 41.8 Nm, observed with the first-generation including reduction-bushing, to 117.5 Nm in the second-generation. Tibia assemblies improved from 18.9 Nm to 56.6 Nm and nail/spacer interfaces in the humerus size range improved the rotational stability from 23 Nm to 34 Nm (Figure 3).

Consequently, peak torque values in femur and tibia improved ~threefold and the maximal torsion in humerus was elevated by 11 Nm (Figure 3). The second-generation clamping area, additionally lead to a change in failure mode. Constant torque plateaus throughout an extended range of rotation were observed compared to the first-generation press-fit that induced frank component failure. Thus, failure modes were additionally improved since peak torques were maintained through an enlarged rotational range with the novel press-fitted surface interface.

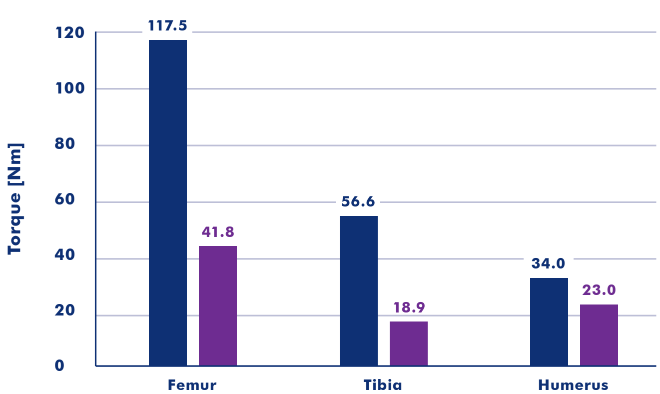


Figure 3: Improved Rotational Stability through Novel Clamping Area. Grooved nails interfacing with a smooth spacer improved the clamping area's mechanical stability between the former system (purple) and the novel design (blue) for Femur, Tibia and Humerus (left to right).

Outlook

Obtaining rigid fixation after resecting large destructive lesions can be difficult with biologic means of fixations, especially in elderly patients that need palliation. The goal after intercalary resections of segmental defects is to achieve immediate load-bearing reconstruction and early return to function.

Endoprothesis with intercalary support supplemented with intramedullary fixation made from titanium currently are the mechanically superior reconstruction method and provide fast mobilization as well as long-term durability [5, 6].

Complications after intercalary resection of lesions with subsequent reconstruction are manifold. Tumor progression, aseptic loosening and structural failures as well as infectious complications have been reported for segmental defect replacement systems (Figure 4). For instance, Aldayami et. al. reported 19 tumor progressions (54%), seven cases of aseptic loosening (20%) and three structural failures (8%) within 35 subjects (Birmingham prothesis) [7]. Morse taper body segments (Stryker, first-generation) lead to two cases of aseptic loosening (10%) and two tumor progressions (10%) in a cohort that included 20 subjects. Lap joint junctions (Stryker, second-generation) increased the amount of aseptic loosening (3/12 patients, 20%) in a follow-up cohort [8]. Other form-fitted junctions (Morse taper, Stanmore) caused nine aseptic dislocations (16%), seven structural failures (13%), two infectious complications (4%) and 16 tumor progressions (30%) in a total of 54 patients [9]. The first-generation of OsteoBridge™ IDSF induced nine structural failures (10%), 13 complications that involved aseptic loosing (15%), two infections (3%) and two tumor progressions (3%) in an ongoing series of 87 patients after initial results were reported [10].

Segmental defect replacement systems provide elevated compression stiffness, flexural rigidity and torsional stability compared to locking plates and intramedullary nails with or without additional cement or allograft segments [2, 3]. Typically, intramedullary fixation that protects the remaining diaphysis is preferable to locking plates due to often insufficient bone quality adjacent to metastatic lesions [11]. External fixators provide equivalent torsional stability and flexural rigidity (Figure 2), however, transdermal fixator pins may dislocate during adjunct, postoperative radiotherapy that may further deteriorate the integrity of surrounding cortical bone. Custom made prosthesis are also available and may be adapted for any topology, though, they generally require extensive planning and several weeks to fabricate.

A titanium spacer assembled with intramedullary nails present favorable mechanical properties when comparing reconstruction options. Clinically employed body segments for intercalary support differ in implant junction types. Press-fitted surface interfaces between nail and spacer or form-fitted male/female junctions are available. Mechanically, form-fitted designs such as lap joints or morse tapers depict elevated torsional stability, though, a minimal resection is required to include the components. Additionally, intraoperative distraction is needed which potentially induces complications such as neuropraxia.

Summary

Preoperative considerations needing attention before selecting an implant are:

1) Overall bone length in relation to

2) The intercalary defect resection width that, in some cases, predetermines the type of junction used for the body segment and finally

3) Stem and intramedullary canal diameters in the remaining diaphysis both proximal and distally

The second generation OsteoBridge™ IDSF novel clamping area was rated safe and effective for the following indications: 1) The long-term stabilization of major bone defects resulting from; 2) Radical bone loss due to tumors and/or metastasis; 3) Bone resections following tumors and/or metastasis; and for 4) use in the diaphyseal region of humerus, tibia and femur.

Consequently, OsteoBridge™ IDSF presents the latest advancement in joint sparing interventions of metastatic disease in patients of advanced age and/or to salvage prior reconstructions. The purpose of the re-introduction of OsteoBridge™ IDSF with a second-generation clamping area was to further reduce implant-associated complications while maintaining modularity and surgical ease-of-use. Moreover, to make a solution for smaller resections clinically available that prevents surgical overextension. First, Merete achieved a threefold improvement in rotational stability through a novel press-fitted interface between the spacers and nails that may potentially minimize structural failures [12]. Mainly, through the removal of the previously needed reduction-bushing (first-generation) and, auxiliary, through the inclusion of grooves on a smooth, sand-blasted clamping interface. Secondarily, this allows surgeons to select varying nail diameters for the intramedullary canal proximal and distal of the resected defects that are replaced with spacers ranging from 40 to 140 mm (10 mm in length) and outer diameters that match the femur, tibia or the humerus. Thirdly, to allow for proper intraoperative rotation, predetermined through preresection marks in the effected bone. Thus, the press-fit feature of the clamping interface allows surgeons to reestablished rotation by realigning the marks after the nails are interlocked or cement is hardened and before the spacer screws are tightened down.

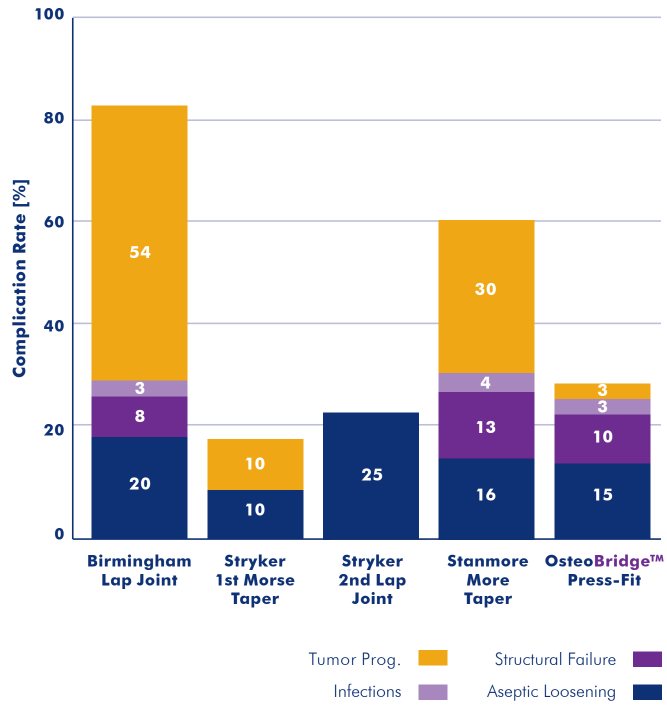


Figure 4: Complication Rates. Tumor progressions, infections, structural failures and aseptic loosening reported for segmental defect replacement systems.

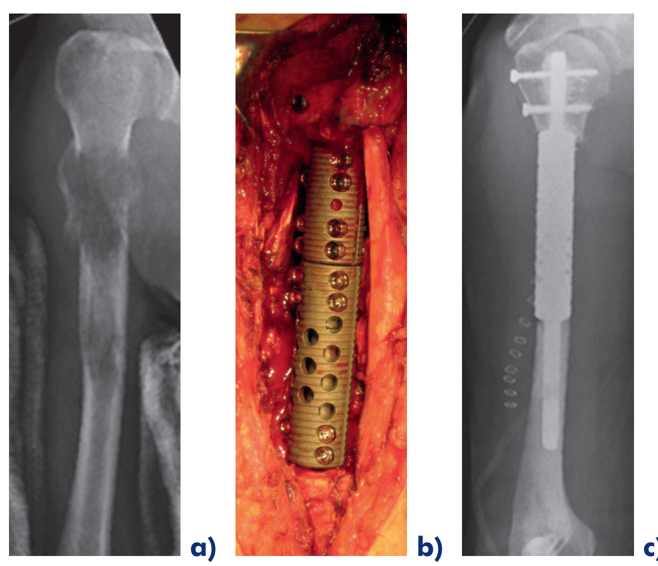
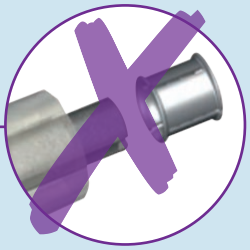


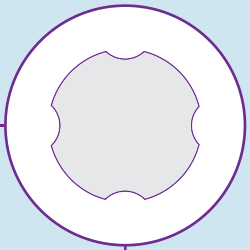
Figure 5: Salvage of Large Defects. 70-year-old patient with a) renal cell carcinoma and two lesions in humerus, fixated with b, c) an interlocked nail proximally, two intercalary spacers and a cemented nail distally.

OsteoBridge™ IDSF

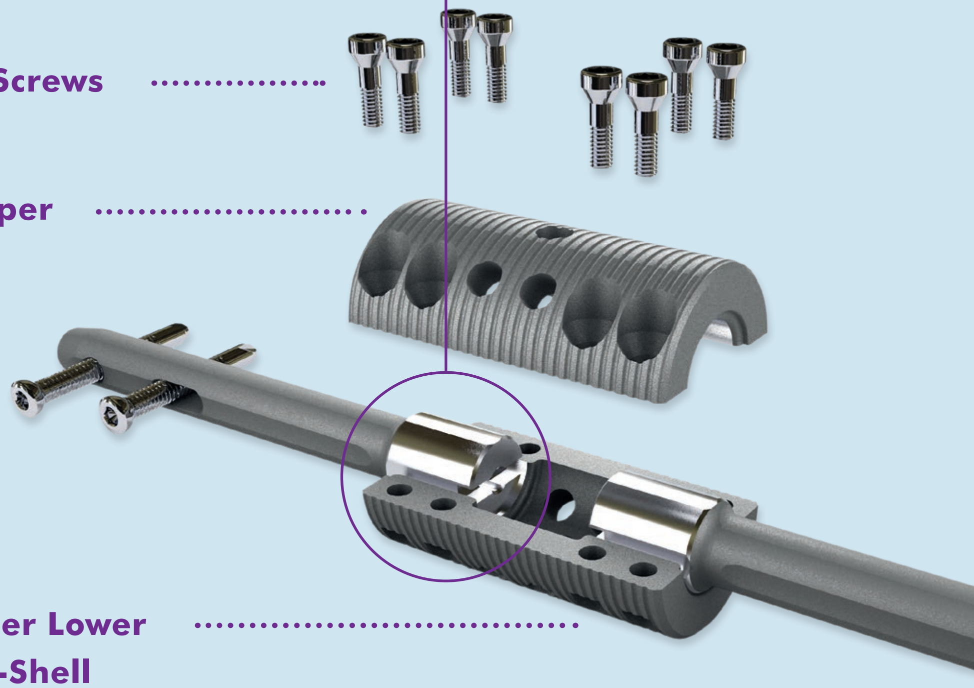
Reduction Bushing Obsolete
Reduces Clamping Surfaces



Clamping Area with Grooves
Elevates Rotational Stability



Press-Fit Preserved
For Surgical Ease-of-Use



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