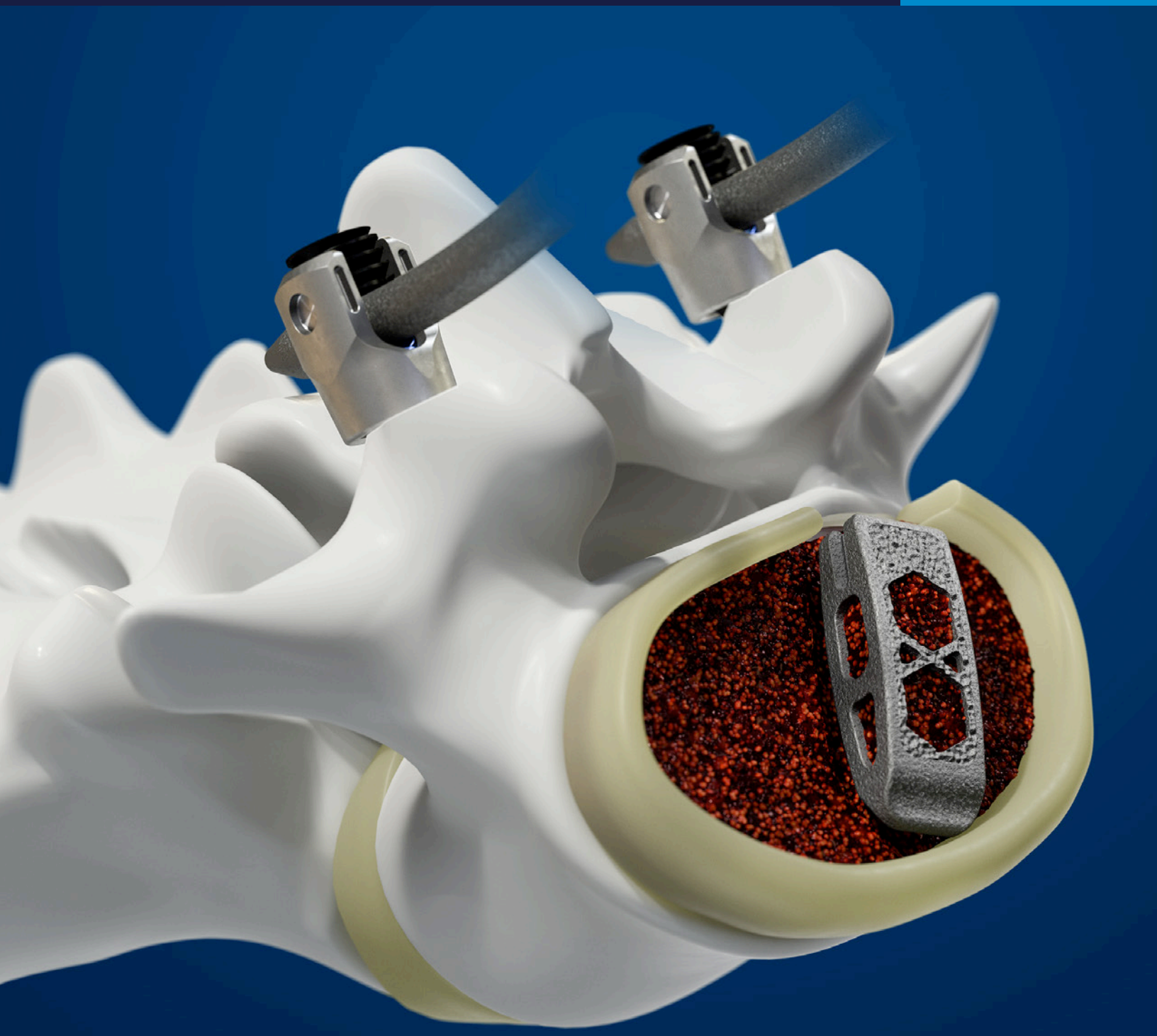
Adaptix™ Interbody System

with Titan nanoLOCK™ Surface Technology

PRODUCT OVERVIEW BROCHURE



Medtronic

FAMILIAR, MEET INNOVATION

TRUSTED DESIGN. ENHANCED FEATURES.

Adaptix™ Interbody System builds on the legacy of the tried and trusted Capstone™ Spinal System, offering a familiar implant footprint with enhanced features for increased strength,[1] subsidence resistance,[1,2,3] easy insertion and bony on-growth[4,5]

Familiar Footprint

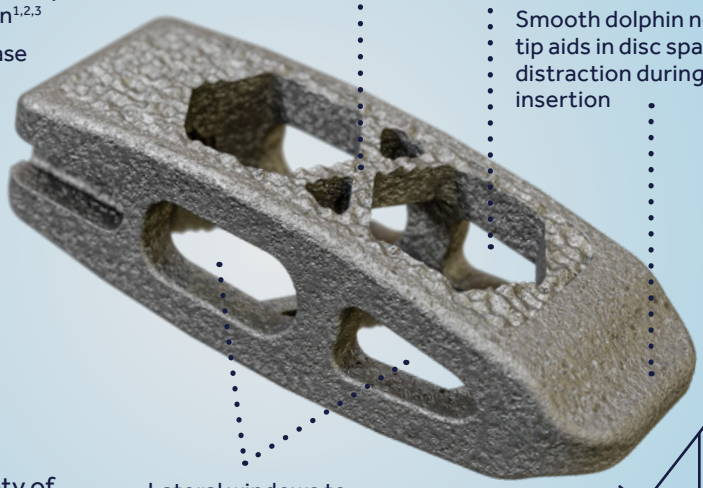
Capstone™ Spinal System

Honeycomb structure

- Allows for more bony surface contact area compared to an open cage design[2]
- Designed to minimize the stress load onto the end plates compared to an open cage design[1,2,3]
- Designed to decrease subsidence compared to an open cage design[1,2,3]
- Acts as an osteoconductive scaffold for bony growth into the implant[4,5]

Open volume design for graft material placement to allow for a continuous column of graft directly in contact with the endplate

Smooth dolphin nose tip aids in disc space distraction during insertion



Available in a variety of lengths and heights to accommodate varying patient anatomy

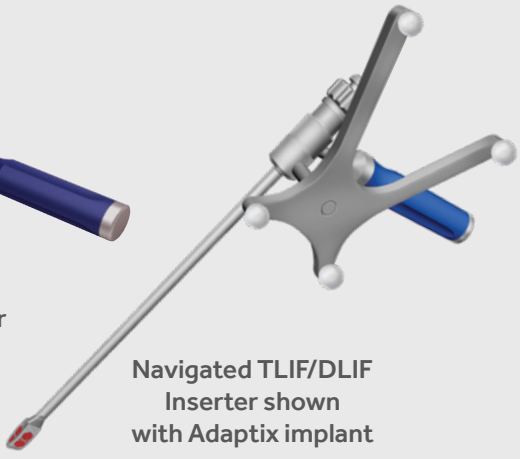
Lateral windows to allow for visualization

Implant width: 10mm

Familiar Instruments

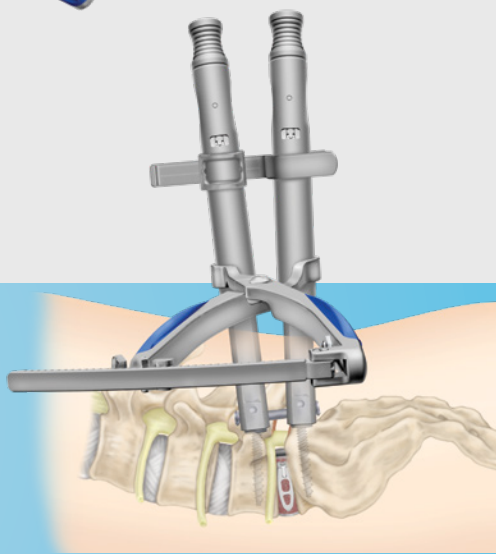
Distractor/Trial
See Surgical Technique for guidance on Trial selection.

Threaded Inserter



Navigated TLIF/DLIF Inserter shown with Adaptix implant

Up to 12° of lordosis can be achieved with posterior compression and final locking of screw-rod instrumentation.[6]



NAVIGATION EFFICIENCY AND CONFIDENCE.

Adaptix™ Interbody System incorporates a Surgical Synergy℠ workflow—streamlined for procedural efficiencies and confidence.

Image

Navigate

Confirm

O-arm™
Surgical Imaging System

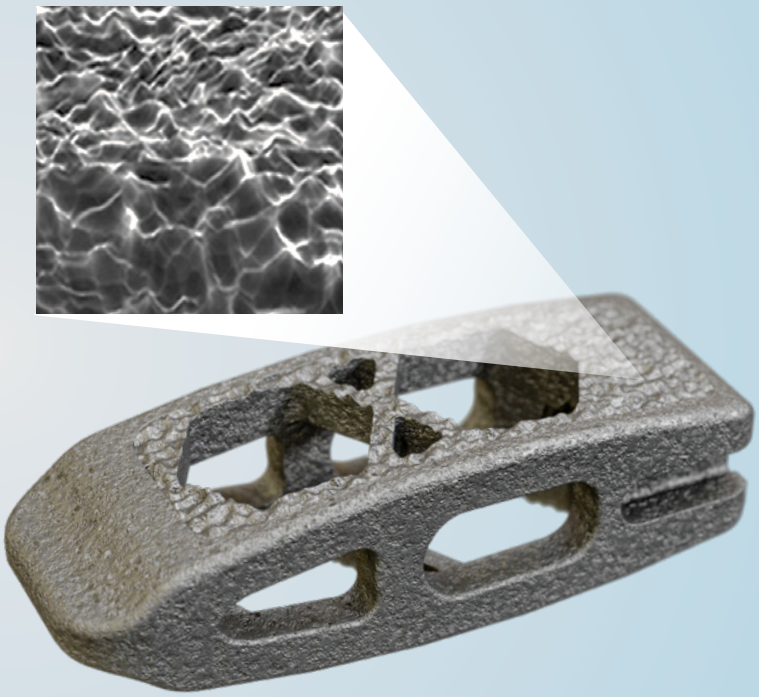
Midas Rex™
Powered Instruments

StealthStation™
Surgical Navigation

SCIENCE-BACKED NANOSURFACE TECHNOLOGY

Adaptix™ Interbody System features Titan nanoLOCK™ Surface Technology:[7]

- The first technology to demonstrate the elements to be considered a Nanotechnology as outlined by the FDA[8]
- Published, peer-reviewed *in vitro* studies demonstrate this surface has the ability to elicit an endogenous cellular and biochemical response attributed to the nanotextured features[†]



Targeted Graft Delivery with Grafton™ DBF Inject

Grafton™ DBF Inject delivers more graft efficiently to the targeted site--giving surgeons a greater chance of delivering the right volume of graft.[*]

*Can be used with Adaptix™ Interbody System when hydrated with BMA.

PRODUCT ORDERING INFORMATION

Adaptix™ 24 and 28mm Implants
SPS03132

Part Number	Description	Quantity
84332406	Adaptix™ 24mm × 6mm	2
84332407	Adaptix™ 24mm × 7mm	2
84332408	Adaptix™ 24mm × 8mm	4
84332409	Adaptix™ 24mm × 8mm	2
84332410	Adaptix™ 24mm × 10mm	4
84332411	Adaptix™ 24mm × 11mm	2
84332412	Adaptix™ 24mm × 12mm	4
84332413	Adaptix™ 24mm × 13mm	2
84332414	Adaptix™ 24mm × 14mm	2
84332806	Adaptix™ 28mm × 6mm	2
84332807	Adaptix™ 28mm × 7mm	2
84332808	Adaptix™ 28mm × 8mm	4
84332809	Adaptix™ 28mm × 9mm	2
84332810	Adaptix™ 28mm × 10mm	4
84332811	Adaptix™ 28mm × 11mm	2
84332812	Adaptix™ 28mm × 12mm	4
84332813	Adaptix™ 28mm × 13mm	2
84332814	Adaptix™ 28mm × 14mm	2
31000000	Generic Suitcase	1

Adaptix™ 34mm Implants
SPS03133

Part Number	Description	Quantity
84333407	Adaptix™ 34mm × 7mm	2
84333408	Adaptix™ 34mm × 8mm	2
84333409	Adaptix™ 34mm × 9mm	2
84333410	Adaptix™ 34mm × 10mm	2
84333411	Adaptix™ 34mm × 11mm	2
84333412	Adaptix™ 34mm × 12mm	2
84333413	Adaptix™ 34mm × 13mm	2
84333414	Adaptix™ 34mm × 14mm	2
8657021	Implant Suitcase	1

Capstone™ Instrument Set
Set Type 2351

Part Number	Description	Quantity
1850078	Triple Generic Outer Case	1
1850079	Generic Outer Lid	1
2980100	6mm Osteotome	1
2980622	6mm × 22mm Distractor/Trial	1
2980626	6mm × 26mm Distractor/Trial	1
2980722	7mm × 22mm Distractor/Trial	1
2980726	7mm × 26mm Distractor/Trial	1
2980822	8mm × 22mm Distractor/Trial	1
2980826	8mm × 26mm Distractor/Trial	1
2980922	9mm × 22mm Distractor/Trial	1
2980926	9mm × 26mm Distractor/Trial	1
2981022	10mm × 22mm Distractor/Trial	1
2981026	10mm × 26mm Distractor/Trial	1
2981122	11mm × 22mm Distractor/Trial	1
2981126	11mm × 26mm Distractor/Trial	1
2981222	12mm × 22mm Distractor/Trial	1
2981226	12mm × 26mm Distractor/Trial	1
2981322	13mm × 22mm Distractor/Trial	1
2981326	13mm × 26mm Distractor/Trial	1
2981422	14mm × 22mm Distractor/Trial	1
2981426	14mm × 26mm Distractor/Trial	1
2981522	15mm × 22mm Distractor/Trial	1
2981526	15mm × 26mm Distractor/Trial	1
2981622	16mm × 22mm Distractor/Trial	1
2981626	16mm × 26mm Distractor/Trial	1
2990001	Threaded Inserter	1
2990003	Threaded Inserter Shaft	1
2990005	Lower Tray	1
2990006	Upper Tray	1
9074002	Slap Hammer	1
2990002	Extractor	1

Scissor Jack™ Expandable Distractor
Set Type 565

Part Number	Description
9198990	Modular Opener
9198991	Variable Distractor Tip Assembly
9198992	Scissor Jack™ Half Tray
9198993	Scissor Jack™ Half Tray Lid

*Navigated interbody trials available

PRODUCT ORDERING INFORMATION

Posterior Microscope Instrument (PMI) Set
Set Type PMI

Part Number	Description
907340	8mm Small Rotate Cutter
907341	10mm Medium Rotate Cuter
907342	12 Large Rotate Cutter
907338	8mm Osteotome
907370	Mallet
907571	4mm Downbiting Pituitary
907610	8mm Pituitary Rongeur
9569536	4mm Pituitary, Ring Handle
9569570	4mm Upbiting Pituitary
907382	Graft Impactor
907380	Dural Retractor
907347	Small Forward Angle Curette
907348	Large Forward Angle Curette
907349	Small Reverse Angle Curette
907350	Large Reverse Angle Curette
907351	Left Angled Cup Curette
907352	Right Angled Cup Curette
907353	Right Straight Cup Curette
907354	Left Straight Cup Curette
907355	Ring Curette
907381	Bayoneted Forceps
2900164	Reamer T-handle
2940357	8mm Shaver
2940350	9mm Shaver
2940351	10mm Shaver
2940352	11mm Shaver
2940353	12mm Shaver
2940354	13mm Shaver
2940355	14mm Shaver
907406	Distracting Osteotome
907408	8mm Distractor
907409	9mm Distractor
907410	10mm Distractor
907411	11mm Distractor
907412	12mm Distractor
907413	13mm Distractor
907414	14mm Distractor
907391	Top Instrument Tray
907390	Middle Instrument Tray
907392	Bottom Instrument Tray
185-064	Generic Metal Case Lid
907393	Outer Case

Navigated 22mm Capstone Trials
SPS02869

CFN	Description	Qty
NAV2050	Capstone™ NAV Trial 8×22mm	1
NAV2051	Capstone™ NAV Trial 10×22mm	1
NAV2052	Capstone™ NAV Trial 12×22mm	1
NAV2053	Capstone™ NAV Trial 14×22mm	1
1850094	Lid, Base Generic	1
NAV2094	Capstone™ NAV 22mm Trial Tray	1

Navigated 26mm Capstone Trials
SPS03127

CFN	Description	Qty
9734555	Capstone™ NAV Trial 8×26mm	1
9734559	Capstone™ NAV Trial 10×26mm	1
9734563	Capstone™ NAV Trial 12×26mm	1
9734567	Capstone™ NAV Trial 14×26mm	1
1850097	Lid, Base Generic	1
3991003	Capstone™ NAV 26mm Trial Tray	1

Navigated TLIF/DLIF Inserter Set
SPS03128

CFN	Description	Qty
9734456	NAV Interbody Inserter	1
9734592	Slap Hammer	1
1850097	Lid, Base Generic	1
2968001	TLIF/DLIF NAV Inserter Tray	1

REFERENCES

1. Comparison of Adaptix and Capstone testing per ASTM F2077and ASTM F2267.
2. Based on surface area measurement.
3. Based on engineering principles.
4. Wennerberg, A., & Albrektsson, T. (2009). Effects of titanium surface topography on bone integration: asystematic review. Clin Oral Implants Res, 20 Suppl 4, 172-184.
5. Gittens, R.A., Olivares-Navarrete, R., Schwartz, Z, Boyan, B.D. (2014). Implant osseointegration and the role of microroughness and nanostructures: lessons for spine implants. Acta Biomater., 10(8), 3363-71.
6. Based on biomechanical study.
7. Based on manufacturing process.
8. FDA Guidance, Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology.

† Based on six peer reviewed published in vitro studies on Titan surface technology.

I. Matteson, J.L., Greenspan, D.C., Tighe, T.B., Gilfoy, N., Stapleton, J.J. Assessing the hierarchical structure of titanium implant surfaces. J Biomed Mater Res B. [In Press] EPub 29 May 2015.

II. Olivares-Navarrete, R., Hyzy S.L., Gittens, R.A., Schneider, J.M., Haithcock, D., Ullrich, P., Schwartz, Z., Boyan, B.D. Rough titanium alloys regulate osteoblast production of angiogenic factors. Spine J. 2013 Nov; 13(11):1563-70.

III. Gittens, R.A., Olivares-Navarrete, R., Schwartz, Z., Boyan, B.D. Implant osseointegration and the role of microroughness and nanostructures: Lessons for spine implants. Acta Biomater 2014 Aug; 10(8): 3363-3371.

IV. Olivares-Navarrete, R., Hyzy S.L., Gittens, R.A., Berg, M.E., Schneider, J.M., Hotchkiss, K., Schwartz, Z., Boyan, B. D. Osteoblast lineage cells can discriminate microscale topographic features on titanium-aluminum-vanadium surfaces. Ann Biomed Eng. 2014 Dec; 42(12): 2551-61.

V. Olivares-Navarrete, R., Hyzy S.L., Slosar, P.J., Schneider, J.M., Schwartz, Z., Boyan, B.D. Implant materials generate different peri-implant inflammatory factors: PEEK promotes fibrosis and micro-textured titanium promotes osteogenic factors. Spine. 2015 Mar; 40(6): 399-404.

VI. Banik, B., Riley, T., Platt, C., Brown, J. Human mesenchymal stem cell morphology and migration on microtextured titanium. Front Bioeng Biotechnol. 2016 May; 4(41) doi: 10.3389/fbioe.2016.00041.

IMPORTANT PRODUCT INFORMATION ON ADAPTIX™ INTERBODY SYSTEM WITH TITAN NANOLOCK™ SURFACE TECHNOLOGY

INDICATIONS

The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

These patients should be skeletally mature and have had six months of nonoperative treatment. The Adaptix™ Interbody System with Titan nanoLOC™ Surface Technology is intended to be used with autograft and/or allogenic bone graft comprised of cancellous, and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate . These implants may be implanted via an open or a minimally invasive posterior approach and/or transforaminal approach.

CONTRAINDICATIONS

This device is not intended for cervical spine use. Contraindications include:

- Infection local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.

POTENTIAL ADVERSE EVENTS

Adverse effects may occur when the device is used either with or without associated instrumentation.

The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include:

- Implant migration.
- Breakage of the device(s).
- Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
- Pressure on the surrounding tissues or organs.

IMPORTANT INFORMATION ON GRAFTON™ DBF INJECT

Grafton™ DBF Inject can be used in orthopaedic or reconstructive bone grafting procedures. The product can also be used in bone grafting procedures in combination with autologous bone or other forms of allograft bone, or alone as a bone graft.

CONTRAINDICATIONS

The presence of infection at the transplantation site is a contraindication for the use of this allograft.

CAUTION

This allograft may contain trace amounts of antibiotics (gentamicin), antiseptic (povidone-iodine) and alcohol solutions. Caution should be exercised if the patient is allergic to these antibiotics or chemicals.

PRECAUTIONS

Despite the viral inactivation and extensive tissue donor selection and qualification processes used in providing this tissue graft, transmission of a communicable disease through the use of this tissue graft is still possible. Bacterial infection at the graft site may also occur. Adverse outcomes potentially attributable to Grafton DBF Inject must be reported promptly to Medtronic. If injecting Grafton DBF inject into the defect site, precaution should be taken not to:

- Over-pressurize the delivery device, as this may lead to extrusion of the device beyond the site of its intended application and damage to the surrounding tissues.
- Over-pressurize the defect site, as this may lead to fat embolization or embolization of the device material into the bloodstream.

SYRINGE/ACCESSORY KIT INTENDED USE

The Graft Preparation and Delivery Device is intended for the delivery of hydrated allograft, autograft or synthetic bone graft materials to an orthopaedic surgical site. In addition, it is designed to facilitate the premixing of bone graft materials with fluids such as I.V. fluids, blood, plasma concentrate, platelet rich plasma, bone marrow or other specified blood components as deemed necessary by the clinical use requirements.

WARNINGS/PRECAUTIONS

There are no specific warnings, precautions, or adverse effects associated with the use of this device.

Medtronic

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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