

**The information contained in this document
is intended for healthcare professionals only.**

stryker[®]
Howmedica
OSTEONICS



X-change[™]
REVISION INSTRUMENTS
S Y S T E M

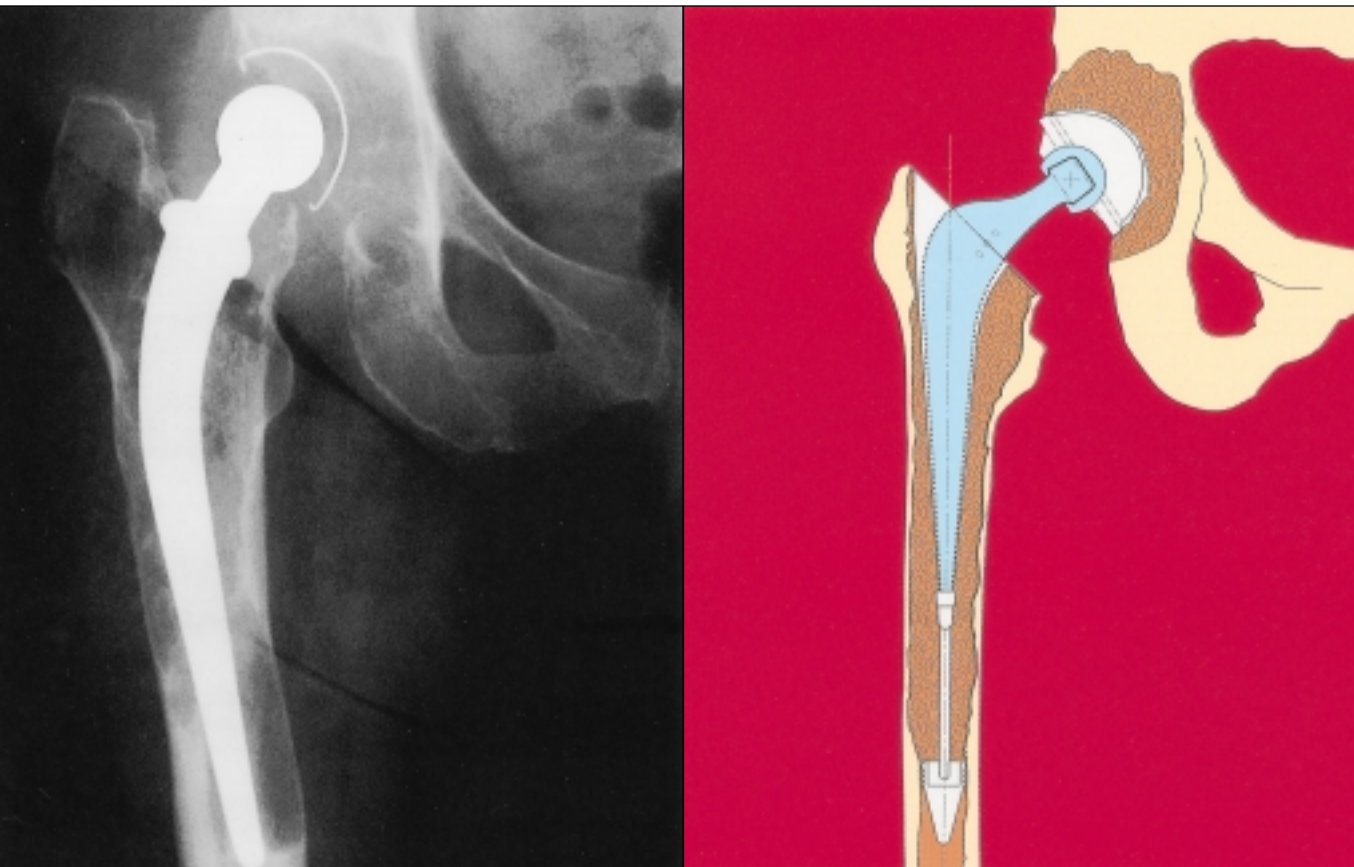
***A method of
regenerating living
bone in the femoral
canal recreating
implant stability
and function.***

The major challenge in revision surgery for failed femoral components in total hip arthroplasty is loss of bone stock secondary to particulate debris and implant instability. Implant instability may lead to further loss of bone stock and a vicious circle is created.

The goals of revision surgery should be the achievement of implant stability and the restoration of bone stock with the required loading of the proximal femur. Clinical experience to date with impaction grafting and the Exeter™ Hip suggests that excellent implant stability is regularly obtainable with impressive restoration of bone stock^{1,4}.

The X-change™ Revision Instruments System, when used correctly, produces a “neomedullary canal” lined with firmly impacted cancellous allograft chips. The system is designed for use with the Exeter™ implant, a prosthesis with over thirty years clinical results². Histological evidence from post mortem studies in patients who have undergone the procedure suggests that a high proportion of the impacted graft is replaced by living host bone with direct contact between new living osteoid and acrylic cement, without the interposition of a soft tissue membrane³.

Irrespective of the anatomy of the distorted and deficient proximal femur, correct usage of the X-change™ Revision Instruments System with impaction grafting is designed to tailor the femur and acetabulum to accept a routinely used size of Exeter™ femoral component and acetabular cup. Specialized revision components have not been required and to date there has been no need for custom-made implants. This can have obvious cost benefits for healthcare providers.



X-change™

REVISION INSTRUMENTS
S Y S T E M



stryker® Howmedica OSTEONICS



Technique

The loose prosthesis is removed along with all of the cement and debris. The femoral canal is washed and occluded with an intramedullary plug, about two centimeters below the most distal lytic area. Any cortical defects or weakness can be corrected with the X-change™ mesh, plates, or suitable cerclage technique.

The canal is then filled with unwashed cancellous allograft bone chips and, using the distal impactors over the guide wire in sequence, bone is packed firmly down onto the plug.

When the level of the impacted chips approximately reaches the proposed level of the tip of the Exeter™ stem to be implanted, the stem shaped proximal impactor is used. As this proximal impactor is driven into the chips over the guide wire, they are forced firmly against the walls of the canal.

These procedures are repeated until the chips reach the proximal end of the canal.

The proximal impactors produce an oversized medullary cavity to accommodate the Exeter™ stem plus an adequate cement mantle. The proximal impactors can be

steered to provide the correct orientation of the new canal.

Achievement of a good clinical result through impaction grafting is reliant on the principles of load transmission from the stem, through the cement to the bone, and achievement of good initial stability. As the implant is fixed to the graft by cement, healing is between the host and the graft.

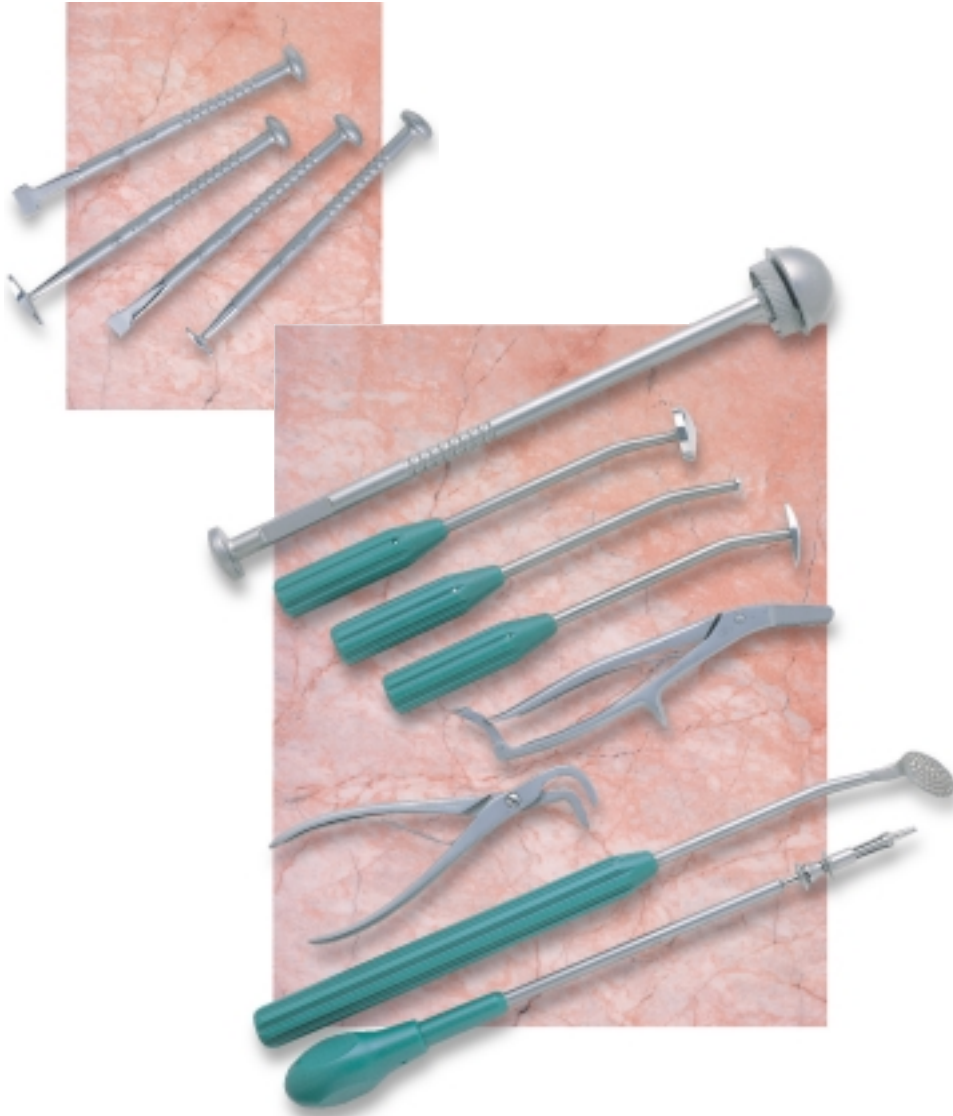
Clinical data shows that allograft bone can be replaced with living cortical bone and implant stability and function are achieved^{1,3}.

Similarly, impaction grafting in the acetabulum can be used to repair defects and encourage bone growth in revision situations. The X-change™ Revision Instruments System offers specially designed instruments to achieve this.

The loose prosthesis is removed along with all cement and debris. The cavity is washed. If necessary, defects can be corrected with the X-change™ mesh.

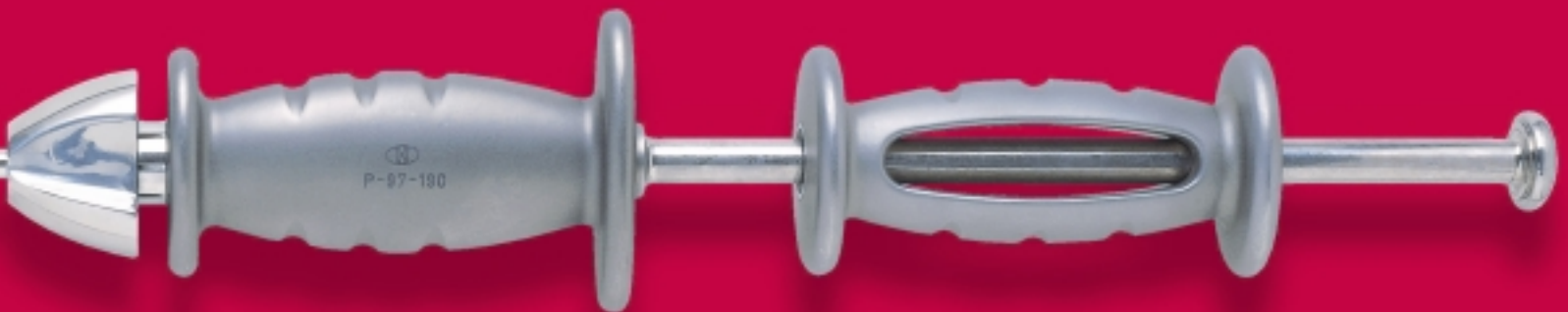
The acetabular impactors are then used to pack the graft in order to reconstruct the shape of the acetabulum, to accommodate the Exeter™ cup plus an adequate cement mantle.





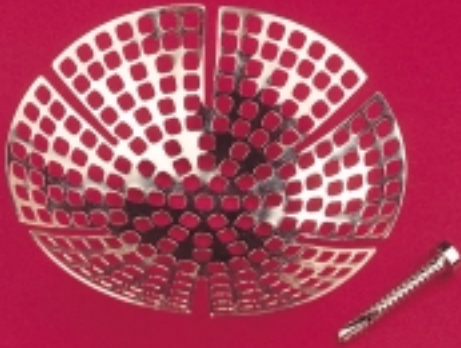
- *Controlled creation of femoral tapering cavity*
- *Controlled creation of acetabular cavity*
- *Controlled creation of cement mantle*
- *Exeter™ Implant with over 30 years of clinical experience**
- *Over fifteen years of experience with impaction grafting & the Exeter™ stem**

*Data on file at Howmedica Osteonics.

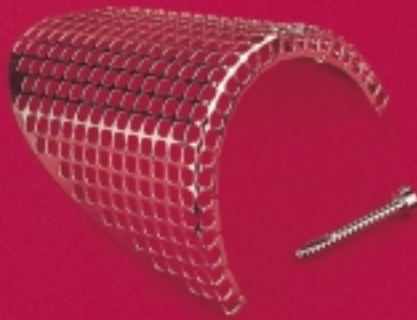


X-change™
REVISION INSTRUMENTS
S Y S T E M

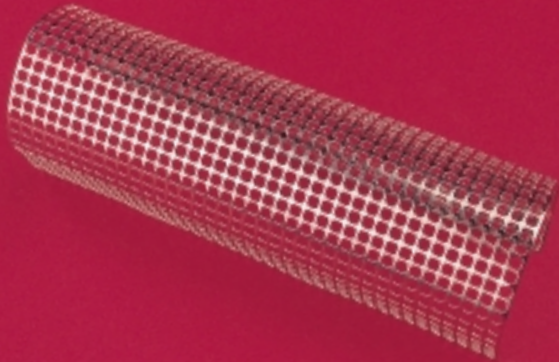
Revision Mesh



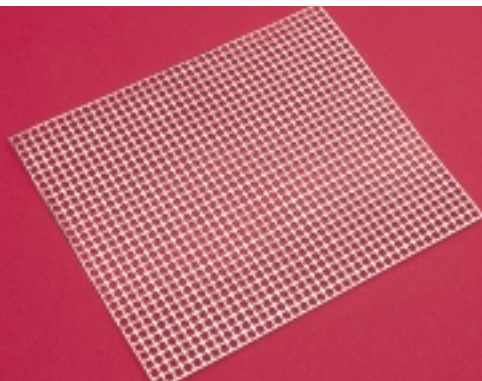
X-change™ Medial Wall Mesh



X-change™ Rim Mesh



X-change™ Femoral Mesh



X-change™ Flat Mesh

The X-change™ Revision Mesh offers two sizes of Medial Wall Mesh, three sizes of Rim Mesh, a Femoral Mesh, a Femoral Anatomic Mesh and a Flat Mesh.

Apart from the Flat Mesh, all the implants are preformed, and are intended to meet the needs of most defect reconstructions and reinforcement. They can be cut and formed to meet individual anatomy requirements using the specially designed cutting and bending instruments.

The specially designed 'petal' shape of the Medial Wall Mesh can be used to help repair defects and act as a constraint for graft. Individual 'petals' can be removed as necessary.

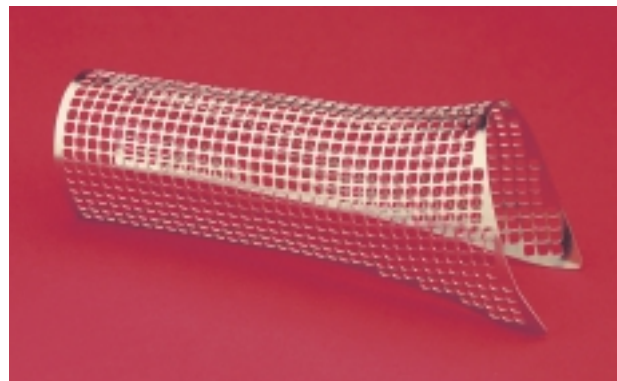
The Rim Mesh is used to provide support on the rim of the acetabulum and can be secured in place using the self-drilling, self-tapping screws.

The Femoral Mesh has been designed to enable the surgeon to add additional strengthening to the femur prior to broaching or impaction grafting.

The Flat Mesh can be used in any application where bone quality is suspect and where additional strengthening and support is indicated.

The Femoral Anatomic Mesh has been designed following surgeon feedback to assist the build-up of the calcar region. It is shaped and fluted to support the proximal femur.

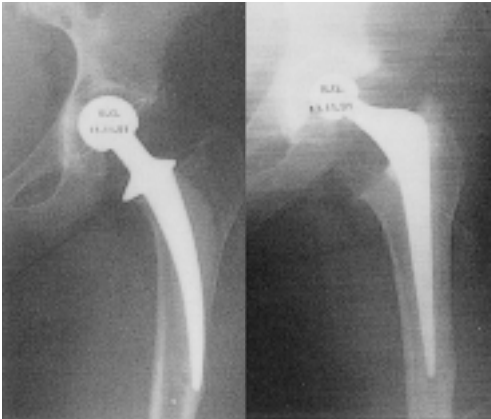
All of the implants are manufactured in high grade stainless steel.



X-change™ Femoral Anatomic Mesh

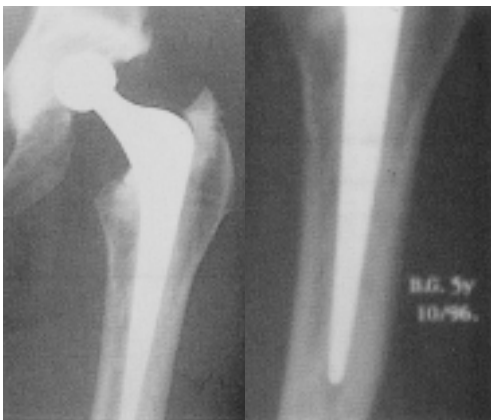
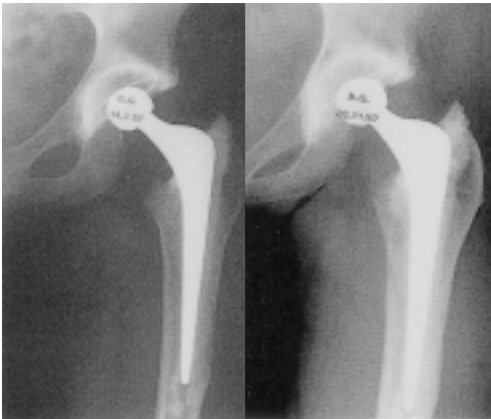
PRE-OP

POST-OP



3 MONTHS

1 YEAR



5 YEARS

**CLOSE UP
IMAGE OF
TRABECULAR
REMODELLING**

CASE STUDY 1 SUMMARY

- 11.91 Pre-Op.
Stem tilted into varus and working loose.
Thinning of cortex at calcar (zone 7) and zone 3 (Lucent lines cup zones 1 and 2 of > 1mm).
- 11.91 Post-Op.
Stem neutral alignment with complete cement mantle and impacted graft.
- 02.92 3 months.
Graft incorporating.
- 11.92 1 year.
Cortical hypertrophy in zones 3 and 7 of femur.
Trabecular remodelling throughout femur.
< 1mm subsidence. Cup very well fixed with only minor (< 1mm) lucency zone 3.
- 10.96 5 years.
Excellent trabecular remodelling. Cortical hypertrophy maintained (< 2mm subsidence as is normal to Exeter stems).

PRE-OP

POST-OP



1 YEAR

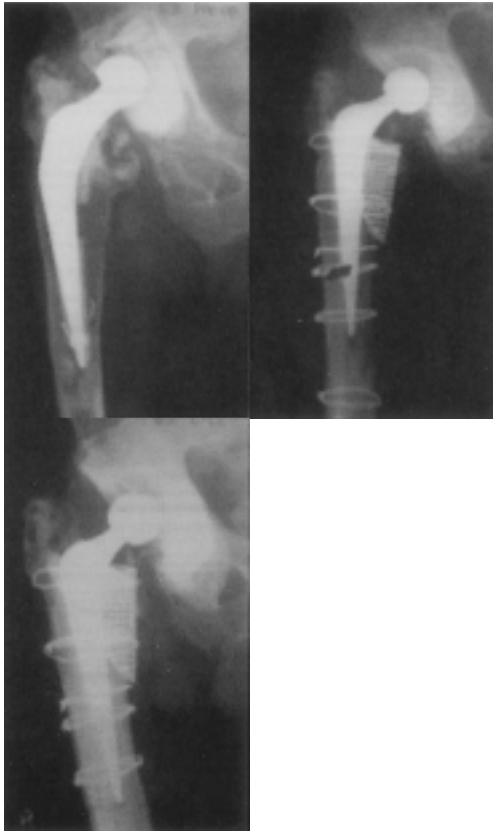
4 YEARS

CASE STUDY 2 SUMMARY

- 06.89 Pre-Op. (Matt Exeter™ stem.)
Endosteal lysis throughout medial and lateral zones (ie. 1, 2, 3, 5, 6, 7). Loss of cortex zone 2. (Acetabulum - lucent lines zone 1 > 1mm, zones 2 and 3 < 1mm).
- 06.89 Post-Op.
Impaction graft in situ with wire at site of distal cyst to retain graft.
- 06.90 1 year.
Healing cyst. Cortical repair, trabecular remodelling.
- 12.94 4 years.
Normal bone quality and cyst healed. (< 1mm subsidence).

PRE-OP

POST-OP



6 MONTHS

CASE STUDY 3 SUMMARY

- 10.96 Pre-Op. (Matt Exeter™ stem.)
Extensive Endosteal Osteolysis and proximal femoral bone loss.
- 11.96 Post Op.
Use of X-change™ mesh to reconstruct proximal femur.
- 06.97 6 months.
Cortical repair.

Femoral Impactors

	0943-1-000	X-change™ III Sliding Hammer
	0943-3-010	X-change™ III Distal Impactor 10mm
	0943-3-012	X-change™ III Distal Impactor 12mm
	0943-3-014	X-change™ III Distal Impactor 14mm
	0943-3-016	X-change™ III Distal Impactor 16mm
	0943-3-018	X-change™ III Distal Impactor 18mm
	0943-3-020	X-change™ III Distal Impactor 20mm
	0942-2-100	Guide Wire Introducer
	0943-6-012	X-change™ III Impactor Half Moon 3mm
	0943-6-013	X-change™ III Impactor Half Moon 6mm
	0943-6-010	X-change™ III Impactor Block 3mm
	0943-6-011	X-change™ III Impactor Block 6mm
	0943-5-000	X-change™ III Connector
	0943-2-001	X-change™ III Guide Wire Self-Tapping
	0943-2-010	X-change™ III Long Stem Guide Wire
	0943-2-101	X-change™ III Drill Diameter 3.2mm
	0943-2-000	X-change™ III Guide Wire
	0943-9-010	X-change™ III Depth Marker Holder
	0943-3-000	X-change™ III Depth Marker (pack of six)
	0943-2-100	X-change™ III Guide Wire Handle
	0943-4-350	X-change™ III Proximal Impactor 35.5
	0943-4-370	X-change™ III Proximal Impactor 37.5 (0)
	0943-4-371	X-change™ III Proximal Impactor 37.5 (1)
	0943-4-372	X-change™ III Proximal Impactor 37.5 (2)
	0943-4-373	X-change™ III Proximal Impactor 37.5 (3)
	0943-4-441	X-change™ III Proximal Impactor 44 (1)
	0943-4-442	X-change™ III Proximal Impactor 44 (2)
	0943-4-443	X-change™ III Proximal Impactor 44 (3)
	0943-4-444	X-change™ III Proximal Impactor 44 (4)
	0943-9-000	X-change™ III Instrument Tray Proximal Impactors
	0943-9-001	X-change™ III Instrument Tray Distal Impactors
	0943-9-002	X-change™ III Instrument Tray Long Stem Impactors
	0942-2-110	Bone Plug 10mm
	0942-2-112	Bone Plug 12mm
	0942-2-114	Bone Plug 14mm
	0942-2-116	Bone Plug 16mm
	0942-2-118	Bone Plug 18mm
	0942-2-120	Bone Plug 20mm

Acetabular Impactors

	0942-7-001	Acetabular Impactor 42mm
	0942-7-002	Acetabular Impactor 46mm
	0942-7-003	Acetabular Impactor 50mm
	0942-7-004	Acetabular Impactor 54mm
	0942-7-005	Acetabular Impactor 58mm
	0942-8-006	Flange for Impactor
	0942-7-006	Impactor 1
	0942-7-007	Impactor 2
	0942-7-008	Impactor, Half Moon
	0942-7-009	Impactor, Sieve
	0942-8-025	X-change™ Medial Wall Mesh - small
	0942-8-020	X-change™ Medial Wall Mesh - large
	0942-8-040	X-change™ Rim Mesh - small
	0942-8-050	X-change™ Rim Mesh - medium
	0942-8-060	X-change™ Rim Mesh - large
	0942-8-010	X-change™ Femoral Mesh
	0942-8-070	X-change™ Femoral Anatomic Mesh
	0942-8-030	Flat Mesh
		X-change™ Self-tapping, Self-drilling screws
	0942-8-000	3.5mm x 10mm screws
	0942-8-001	3.5mm x 15mm screws
	0942-8-002	3.5mm x 20mm screws
	0942-8-003	3.5mm x 25mm screws
	0942-8-004	3.5mm x 30mm screws
	0942-8-005	3.5mm x 35mm screws
	6885-3-140	Tubular Bending Pliers
	0942-7-011	X-change™ Mesh Cutter
	0942-7-012	X-change™ Mesh Pliers
	0942-7-010	X-change™ Acetabular Screwdriver








Patents Pending

Central Range

ORTHINOX™ FEMORAL STEMS	STEM	RASP
35.5 Offset Stem (CDH Small)	0580-0-351	0580-9-351
37.5 (0) Offset Stem (CDH Large)	0580-0-352	0580-9-352
No.1 - 37.5mm Offset Stem	0580-0-371	0580-9-371
No.2 - 37.5mm Offset Stem	0580-0-372	0580-9-372
No.3 - 37.5mm Offset Stem	0580-0-373	0580-9-373
No.1 - 44mm Offset Stem	0580-0-441	0580-9-441
No.2 - 44mm Offset Stem	0580-0-442	0580-9-442
No.3 - 44mm Offset Stem	0580-0-443	0580-9-443
No.4 - 44mm Offset Stem	0580-0-444	0580-9-444

EXETER™ LONG STEMS	STEM
Exeter™ 205mm Tapered Long Stem 44mm offset No.2	0580-2-442
Exeter™ 200mm Long Stem 44mm Offset No.3	0580-0-200
Exeter™ 220mm Long Stem 44mm Offset No.3	0580-0-220
Exeter™ 240mm Long Stem 44mm Offset No.3	0580-0-240
Exeter™ 260mm Long Stem 44mm Offset No.3	0580-0-260

X-CHANGE™ III LONG STEM INSTRUMENTS

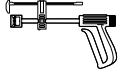
X-change™ III Graft Borer	0943-3-100	
X-change™ III Proximal Starter Impactor No. 30943-4-160		
X-change™ III Proximal Impactor 200 (3)	0943-4-200	
X-change™ III Proximal Impactor 205 (2)	0943-4-202	
X-change™ III Proximal Impactor 220 (3)	0943-4-220	
X-change™ III Proximal Impactor 240 (3)	0943-4-240	
X-change™ III Proximal Impactor 260 (3)	0943-4-260	

ORTHINOX™ FEMORAL HEADS	IMPLANTS	TRIAL
FEMORAL HEAD 22mm	0586-0-022	0586-9-022
FEMORAL HEAD 26mm -3mm NECK	0586-0-326	0586-9-326
FEMORAL HEAD 26mm	0586-0-026	0586-9-026
FEMORAL HEAD 26mm +5mm NECK	0586-5-026	0586-9-526
FEMORAL HEAD 28mm -3mm NECK	0586-0-328	0586-9-328
FEMORAL HEAD 28mm	0586-0-028	0586-9-028
FEMORAL HEAD 28mm +5mm NECK	0586-5-028	0586-9-528
FEMORAL HEAD 30mm -3mm NECK	0586-0-330	0586-9-330
FEMORAL HEAD 30mm	0586-0-030	0586-9-030
FEMORAL HEAD 30mm +5mm NECK	0586-5-030	0586-9-530
FEMORAL HEAD 32mm -3mm NECK	0586-0-332	0586-9-332
FEMORAL HEAD 32mm	0586-0-032	0586-9-032
FEMORAL HEAD 32mm +5mm NECK	0586-5-032	0586-9-532

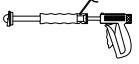
ZIRCONIA CERAMIC HEADS	IMPLANTS	TRIAL
Femoral Head 28mm	4658-2-802	0586-9-028
Femoral Head 28mm + 5mm neck	4658-2-801	0586-9-528
Femoral Head 32mm - 3mm neck	4658-3-203	0586-9-332
Femoral Head 32mm	4658-3-202	0586-9-032
Femoral Head 32mm + 5mm neck	4658-3-201	0586-9-532

Exeter™ Instruments

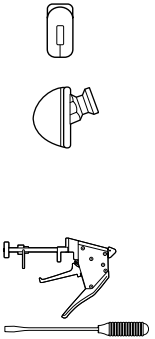
STEM INSTRUMENTS	
EXETER™ UNIVERSAL STEM INTRODUCER	0930-3-002
EXETER™ LEG-LENGTH GAUGE	0930-3-400



CUP INSTRUMENTS	
CUP INTRODUCER	0927-4-026
LATERAL CUP INTRODUCER	0927-4-030
UNIVERSAL CUP PUSHER	0927-2-500



CEMENT SECURITY SYSTEM	
STEM SEAL SMALL 5 PACK	0937-3-015
STEM SEAL LARGE 5 PACK	0937-3-025
PROXIMAL FEMORAL SEAL BACKING PLATE	0937-8-100
PROXIMAL FEMORAL SEAL SMALL 5 PACK	0937-8-005
PROXIMAL FEMORAL SEAL LARGE 5 PACK	0937-8-015
PROXIMAL FEMORAL SEAL X-CHANGE 5 PACK	0937-8-025
STRYKER GUN	6205-1-510
MIXING SPATULA	0183-0-020



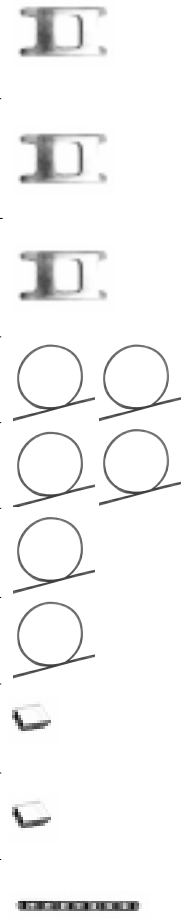
Dall-Miles™ Instruments

	CAT. NO.
DOUBLE-SIDED TENSIONER	6704-9-350
SINGLE-SIDED TENSIONER	6704-9-320
TENSION RETAINING DEVICE	6704-9-250
FEMORAL CABLE PASSERS	6704-9-800/820
TROCHANTERIC CABLE PASSERS	6704-9-760/770
SLEEVE HOLDING FORCEPS	6704-9-520
GRIP INTRODUCER	6704-9-715
TROCHANTER FORCEPS	6704-9-550
GRIP IMPACTOR	6704-9-720
CRIMP TOOL	6704-9-150
FLUSH CUTTER	6704-9-420
REMOVAL CUTTER	6704-9-460
ADDITIONAL INSTRUMENTS (not shown)	
6.50" S/S PLATE TEMPLATE	3704-7-100
8.00" S/S PLATE TEMPLATE	3704-7-110
10.00" S/S PLATE TEMPLATE	3704-7-120
12.00" S/S PLATE TEMPLATE	3704-7-130
CRIMP TOOL GAUGE	6704-9-120



Dall-Miles™ Stainless Steel Implants

	CAT. NO.
STAINLESS STEEL TROCHANTER CABLE GRIP SMALL 1.6MM HOLE	0023-0-100
STAINLESS STEEL TROCHANTER CABLE GRIP MEDIUM 2.00MM HOLE	0023-0-200
STAINLESS STEEL TROCHANTER CABLE GRIP LARGE 2.0MM HOLE	0023-0-400
STAINLESS STEEL CABLES (SET OF TWO) 1.5MM DIAMETER, LENGTH 750MM	0023-0-001
STAINLESS STEEL CABLES (SET OF TWO) 2.0MM DIAMETER, LENGTH 750MM	0023-0-002
STAINLESS STEEL CABLE 1.5MM DIAMETER, LENGTH 750MM	0023-0-010
STAINLESS STEEL CABLE 2.0MM DIAMETER, LENGTH 750MM	0023-0-020
STAINLESS STEEL CABLE SLEEVE SMALL 1.6MM HOLE	0023-0-515
STAINLESS STEEL CABLE SLEEVE MEDIUM 2.0MM HOLE	0023-0-520



Stainless Steel Self Compression Bone Plates (Accepts 4.5mm Screws)			
Implant Cat No.	Holes	Grooves	Plate Length Inches
3704-3-100	5	6	6.5
3704-3-110	7	8	8.0
3704-3-120	9	10	10.0
3704-3-130	11	12	12.0



References

1. Impacted Cancellous Allografts and Cement for Revision Total Hip Arthroplasty

G. A. GIE, L. LINDER, R. S. M. LING, J-P. SIMON, T. J. J. H. SLOOFF, A. J. TIMPERLEY

From Princess Elizabeth Orthopaedic Hospital, Exeter, England and Saint Radboud Academisch Ziekenhuis, Nijmegen, The Netherlands
J Bone Joint Surg (Br) 1993;75-B:14-21.

2. Clinical Experience with Primary Cemented Total Hip Arthroplasty

R. S. M. LING

Chir Organi Mov LXXVII 373-381-1197

3. Histology of Impaction Cancellous Grafting in the Femur

R. S. M. LING, A. J. TIMPERLEY, L. LINDER.

J Bone Joint Surg. (Br) 1993;75-B:693-6

4. Acetabular and Femoral Reconstruction with Impacted Graft and Cement

T. J. J. H. SLOOFF, P. BUMA, B. W. SCHREURS, J. W. SCHIMMEL, R. HUISKES, J. GARDENIERS

CLINICAL ORTHOPAEDICS, March, 1996
Volume 324
Lippincott-Raven Publishers.

- **Bone grafting in Total Hip Replacement for Acetabular Protrusion.**

T. J. J. H. SLOOFF, R. HUISKES, J. VAN HORN, A. J. LEMMENS (1984)
Acta Orthop. Scand 55, 593-96.

- **Cemented Fixation with Bone Grafts.**

T. J. J. H. SLOOFF, J. W. SCHIMMEL, P. BUMA, (1993)
Orthop. Clin. of N.A., 24, 4, 667-677.

stryker[®]
Howmedica
OSTEONICS