United®
Orthopedic Corporation

GTF II™ Stem

A solution of proximal femoral bone loss

Specifications

Implant

GTF II Stem

Catalog No.	Description		
1108-3041	Ø 9 mm,	45 mm,	130 mm
1108-3043	Ø 9 mm,	45 mm,	160 mm
1108-3051	Ø 9 mm,	55 mm,	130 mm
1108-3053	Ø 9 mm,	55 mm,	160 mm
1108-5041	Ø 11 mm,	45 mm,	130 mm
1108-5043	Ø 11 mm,	45 mm,	160 mm
1108-5051	Ø 11 mm,	55 mm,	130 mm
1108-5053	Ø 11 mm,	55 mm,	160 mm

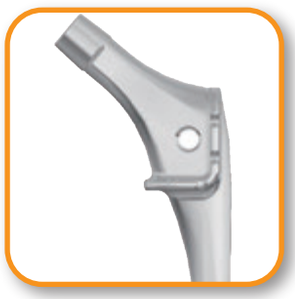
Accessories

Catalog No.	Description	
1904-5010	Centralizer	Ø 10 mm
1904-5011	Centralizer	Ø 11 mm
1904-5012	Centralizer	Ø 12 mm
1904-5013	Centralizer	Ø 13 mm
1904-5014	Centralizer	Ø 14 mm

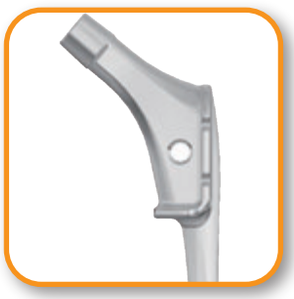
Catalog No.	Description	Ø A	Ø B
1905-7007	Cement Stopper	Ø 7 mm	Ø 13 mm
1905-7008	Cement Stopper	Ø 8 mm	Ø 14 mm
1905-7009	Cement Stopper	Ø 9 mm	Ø 15 mm
1905-7010	Cement Stopper	Ø 10 mm	Ø 16 mm
1905-7011	Cement Stopper	Ø 11 mm	Ø 17 mm
1905-7012	Cement Stopper	Ø 12 mm	Ø 18 mm
1905-7013	Cement Stopper	Ø 13 mm	Ø 19 mm
1905-7014	Cement Stopper	Ø 14 mm	Ø 20 mm
1905-7015	Cement Stopper	Ø 15 mm	Ø 21 mm
1905-7016	Cement Stopper	Ø 16 mm	Ø 22 mm

GTF II stem - an alternative for severe proximal bone loss

Key Features



45 mm Resection Level

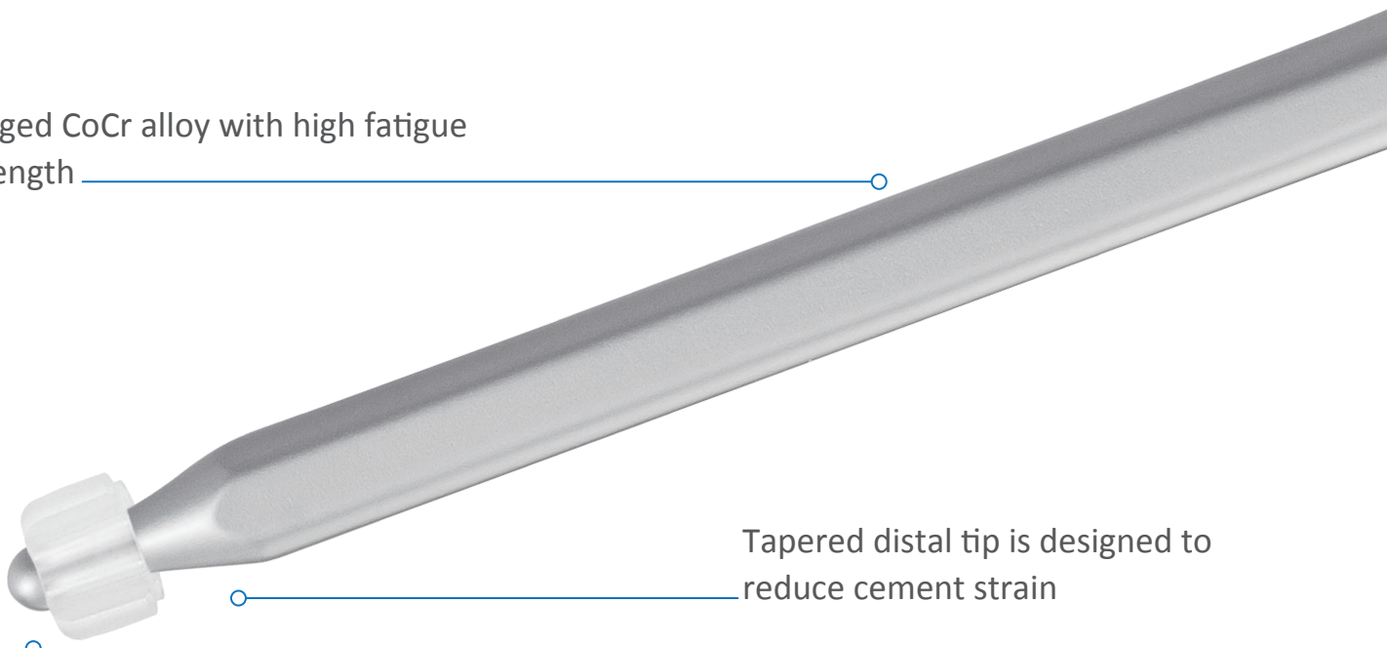


55 mm Resection Level

Two resection levels benefit surgical flexibility

Medial flare design ensures the rotational stability

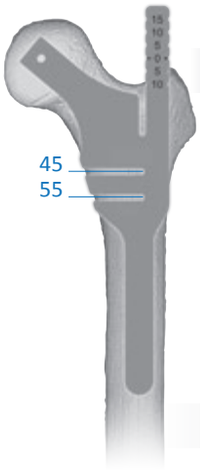
Forged CoCr alloy with high fatigue strength



Tapered distal tip is designed to reduce cement strain

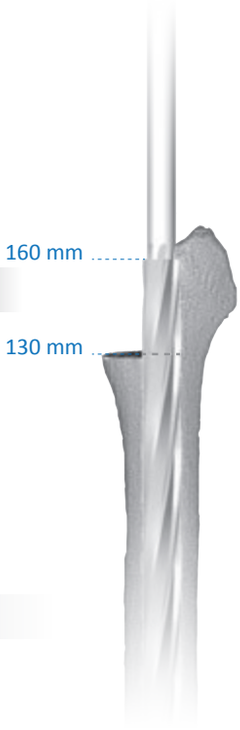
Distal centralizer equalizes cement mantle and ensures correct stem alignment

Surgical procedure



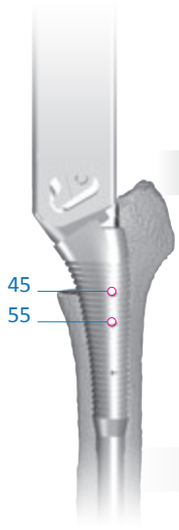
1. Femoral resection

The proximal femoral cut can be determined via the level of bone loss. The 45mm calcar resection level is appropriate for bone loss above lesser trochanter whereas the 55mm resection is designed for bone loss below lesser trochanter. Use the **GTF II Stem Resection Guide** to mark the desired bone cut and finish femoral resection. Thorough debridement of the femur and accurate preparation of the resected platform is important for prosthesis seating.



2. Canal reaming

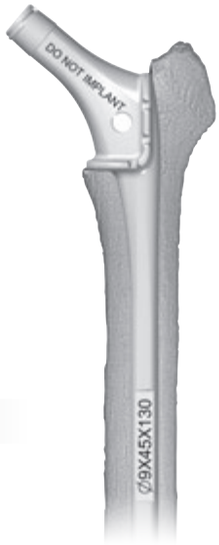
The length options of the stem include 130mm and 160mm. For 130mm length, reaming to the depth marking on the **GTF II Stem Reamer** while a full length reaming is required for 160mm stem. It's recommended that final reamer diameter can be 3mm larger or more to allow a proper cement mantle thickness.



3. Canal broaching

Shape the proximal femoral canal by using the **GTF II Stem Broach** and the **Broach Handle**. The two holes on the broach indicates the reference of 45mm and 55mm calcar resection, stop at correct calcar resection selected.

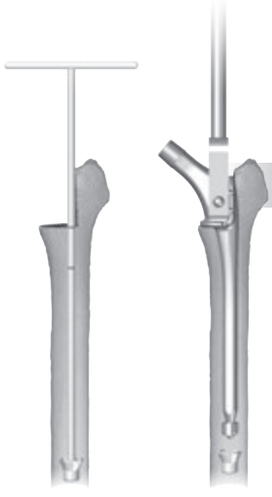
Caution: Do not fully advance the broach into canal.



4. Trial reduction

Once the canal is well-prepared, utilize **GTF II Stem Trail** together with the acetabular system to perform trial reduction for desired assessment of leg length and functional check.

Note: The size and label on the trial are the same with actual implant without the thickness of cement mantle.



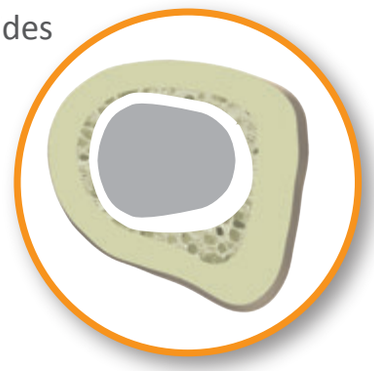
5. Stem insertion

Insert the proper **Cement Stopper** into canal with the **GTF II Cement Restrictor Inserter**, which shall be below the stem tip in 20 mm. Cement is then injected into canal and pressurized. According to the size of the final reamer to select the proper **Centralizer** attached at the tip of the stem. Use **GTF II Stem Inserter** together with the **GTF II Stem Head Pin** to hold and place the stem into canal. If needed, wiring the greater trochanter with stem via the cutouts of lateral flange and through hole.

12/14 Morse taper with
130°neck shaft angle

Cutouts and through hole design for
additional wire fixation

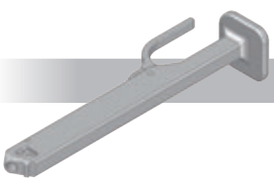
Trapezoidal cross-section provides
biological stress distribution



Catalog No.	Description
9108-5303	GTF II Stem Inserter

Catalog No.	Description
9108-5304	GTF II Stem Head Pin

Catalog No.	Description
9108-6309	GTF II Stem Broach, # 9
9108-6311	GTF II Stem Broach, # 11

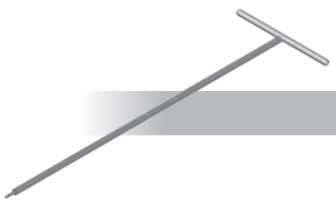


Catalog No.	Description
9104-6103-RA	Broach Handle

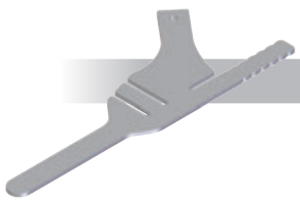
Catalog No.	Description
9108-8310	GTF II Stem Case

Instruments

Catalog No.	Description
1108-4041	GTF II Stem trial Ø 9 mm 45 mm
1108-4051	GTF II Stem trial Ø 9 mm 55 mm
1108-6041	GTF II Stem trial Ø 11 mm 45 mm
1108-6051	GTF II Stem trial Ø 11 mm 55 mm



Catalog No.	Description
9108-1101	GTF II Cement Restrictor Inserter



Catalog No.	Description
9108-2301	GTF II Stem Resection Guide

Catalog No.	Description
9108-3310	GTF II Stem Reamer, Ø 10
9108-3311	GTF II Stem Reamer, Ø 11
9108-3312	GTF II Stem Reamer, Ø 12
9108-3313	GTF II Stem Reamer, Ø 13
9108-3314	GTF II Stem Reamer, Ø 14

Safety Statement – GTF II Stem

Important
This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see the package insert for complete device information.

INDICATIONS
For use as a Bipolar Hip Replacement
Femoral head/neck/intertrochanteric factures or non-unions.
Aseptic necrosis of the femoral head.
Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.
For use as a Total Hip Replacement
1.Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
2.Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3.Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

CONTRAINDICATIONS
1.Any active or suspected latent infection in or about the hip joint.
2.Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
3.Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
4.Skeletal immaturity.
5.Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.
6.For use as a Bipolar Hip Replacement, pathological conditions of the acetabulum which would prevent achieving adequate range of motion, appropriate head stability, and/or a well-seated and supported smooth acetabular articulation of the head.

WARNINGS
1.Discard all damaged or mishandled implants.
2.Never reuse an implant, even though it may appear undamaged. Reuse of this product will cause the risk of cross infection and unpredictable health threat. Polished bearing areas and machined taper surfaces must not come in contact with hard or abrasive surfaces.
3.Bearing areas must always -be clean and free of debris prior to assembly.
4.At time of assembly, machined taper surfaces must be clean and dry to ensure proper seating and assembly security.
5.Improper seating of the head or Endo neck extension may result in a discrepancy in neck length, component disassociation and/or dislocation.
6.Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
7.Infra-operative preparation and implantation of a femoral stem component can result in cracks of the proximal femur. The application of prophylactic cerclage wiring to the proximal femur may aid in the prevention of femoral cracks, crack propagation or their displacement
8.Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopedic device.
9.UOC strongly advises against the use of another manufacturer's tapered head, PMMA spacer or acetabular component with any UOC femoral stem component. Any such use will negate the responsibility of UOC for the performance of the resulting mixed component implant.
10.Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize.

PRECAUTIONS
1.Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Patients should be instructed in the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. If the patient is involved in an occupation or activity, which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
2.Appropriate selection, placement and fixation of the femoral stem and/or acetabular components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanical and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.
3.Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects.

For more information about UOC products, visit our web site at www.uoc.com.tw

United® Orthopedic Corporation

Each Step **We Care**

www.uoc.com.tw

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