

特材代碼：FBN05RFNA0S1

中文品名：“信迪思”進階型逆行股骨髓內釘系統

英文品名：“Synthes”RFN-Advanced Retrograde Femoral Nailing System (RFNA)

許可證字號：衛部醫器輸字第 036428 號+衛署醫器輸字第 018775 號

自 113 年 11 月 1 日生效，擴增產品型號：

衛署醫器輸字第 018775 號

Locking screw:

04.005.516；04.005.518；04.005.520；04.005.522；04.005.524；04.005.526；
04.005.528；04.005.530；04.005.532；04.005.534；04.005.536；04.005.538；
04.005.540；04.005.542；04.005.544；04.005.546；04.005.548；04.005.550；
04.005.554；04.005.558；04.005.562；04.005.566；04.005.570；04.005.575；
04.005.580；04.005.585；04.005.590；
04.015.520；04.015.525；04.015.530；04.015.535；04.015.540；04.015.545；
04.015.550；04.015.555；04.015.560；04.015.565；04.015.570；04.015.575；
04.015.580

自 113 年 11 月 1 日生效，重整產品型號：

Locking screw:

衛部醫器輸字第 036428 號

未滅菌：

04.045.026；04.045.028；04.045.030；04.045.032；04.045.034；04.045.036；04.045.038；
04.045.040；04.045.042；04.045.044；04.045.046；04.045.048；04.045.050；04.045.052；
04.045.054；04.045.056；04.045.058；04.045.060；04.045.062；04.045.064；04.045.066；
04.045.068；04.045.070；04.045.072；04.045.074；04.045.076；04.045.078；04.045.080；
04.045.082；04.045.084；04.045.086；04.045.088；04.045.090；04.045.095；04.045.100；
04.045.105；04.045.110；04.045.115；04.045.120；04.045.326；04.045.328；04.045.330；
04.045.332；04.045.334；04.045.336；04.045.338；04.045.340；04.045.342；04.045.344；
04.045.346；04.045.348；04.045.350；04.045.352；04.045.354；04.045.356；04.045.358；
04.045.360；04.045.362；04.045.364；04.045.366；04.045.368；04.045.370；04.045.372；
04.045.374；04.045.376；04.045.378；04.045.380；04.045.382；04.045.384；04.045.386；
04.045.388；04.045.390；04.045.395；04.045.400；04.045.405；04.045.410；04.045.415；
04.045.420

滅菌：

04.045.026S；04.045.028S；04.045.030S；04.045.032S；04.045.034S；04.045.036S；
04.045.038S；04.045.040S；04.045.042S；04.045.044S；04.045.046S；04.045.048S；
04.045.050S；04.045.052S；04.045.054S；04.045.056S；04.045.058S；04.045.060S；
04.045.062S；04.045.064S；04.045.066S；04.045.068S；04.045.070S；04.045.072S；
04.045.074S；04.045.076S；04.045.078S；04.045.080S；04.045.082S；04.045.084S；
04.045.086S；04.045.088S；04.045.090S；04.045.095S；04.045.100S；04.045.105S；
04.045.110S；04.045.115S；04.045.120S；04.045.326S；04.045.328S；04.045.330S；
04.045.332S；04.045.334S；04.045.336S；04.045.338S；04.045.340S；04.045.342S；
04.045.344S；04.045.346S；04.045.348S；04.045.350S；04.045.352S；04.045.354S；
04.045.356S；04.045.358S；04.045.360S；04.045.362S；04.045.364S；04.045.366S；
04.045.368S；04.045.370S；04.045.372S；04.045.374S；04.045.376S；04.045.378S；
04.045.380S；04.045.382S；04.045.384S；04.045.386S；04.045.388S；04.045.390S；

04.045.395S ; 04.045.400S ; 04.045.405S ; 04.045.410S ; 04.045.415S ; 04.045.420S

滅菌(Tube Packaging) :

04.045.026TS ; 04.045.028TS ; 04.045.030TS ; 04.045.032TS ; 04.045.034TS ; 04.045.036TS ;
04.045.038TS ; 04.045.040TS ; 04.045.042TS ; 04.045.044TS ; 04.045.046TS ; 04.045.048TS ;
04.045.050TS ; 04.045.052TS ; 04.045.054TS ; 04.045.056TS ; 04.045.058TS ; 04.045.060TS ;
04.045.062TS ; 04.045.064TS ; 04.045.066TS ; 04.045.068TS ; 04.045.070TS ; 04.045.072TS ;
04.045.074TS ; 04.045.076TS ; 04.045.078TS ; 04.045.080TS ; 04.045.082TS ; 04.045.084TS ;
04.045.086TS ; 04.045.088TS ; 04.045.090TS ; 04.045.095TS ; 04.045.100TS ; 04.045.105TS ;
04.045.110TS ; 04.045.115TS ; 04.045.120TS

04.045.326TS ; 04.045.328TS ; 04.045.330TS ; 04.045.332TS ; 04.045.334TS ; 04.045.336TS ;
04.045.338TS ; 04.045.340TS ; 04.045.342TS ; 04.045.344TS ; 04.045.346TS ; 04.045.348TS ;
04.045.350TS ; 04.045.352TS ; 04.045.354TS ; 04.045.356TS ; 04.045.358TS ; 04.045.360TS ;
04.045.362TS ; 04.045.364TS ; 04.045.366TS ; 04.045.368TS ; 04.045.370TS ; 04.045.372TS ;
04.045.374TS ; 04.045.376TS ; 04.045.378TS ; 04.045.380TS ; 04.045.382TS ; 04.045.384TS ;
04.045.386TS ; 04.045.388TS ; 04.045.390TS ; 04.045.395TS ; 04.045.400TS ; 04.045.405TS ;
04.045.410TS ; 04.045.415TS ; 04.045.420TS

衛署醫器輸字第 018775 號

04.005.516 ; 04.005.518 ; 04.005.520 ; 04.005.522 ; 04.005.524 ; 04.005.526 ; 04.005.528 ;
04.005.530 ; 04.005.532 ; 04.005.534 ; 04.005.536 ; 04.005.538 ; 04.005.540 ; 04.005.542 ;
04.005.544 ; 04.005.546 ; 04.005.548 ; 04.005.550 ; 04.005.554 ; 04.005.558 ; 04.005.562 ;
04.005.566 ; 04.005.570 ; 04.005.575 ; 04.005.580 ; 04.005.585 ; 04.005.590 ;
04.015.520 ; 04.015.525 ; 04.015.530 ; 04.015.535 ; 04.015.540 ; 04.015.545 ; 04.015.550 ;
04.015.555 ; 04.015.560 ; 04.015.565 ; 04.015.570 ; 04.015.575 ;
04.015.580

Nail:

衛部醫器輸字第 036428 號

Ø 9 mm

04.233.916S ; 04.233.920S ; 04.233.924S ; 04.233.928S ; 04.233.930S ; 04.233.932S ;
04.233.934S ; 04.233.936S ; 04.233.938S ; 04.233.940S ; 04.233.942S ; 04.233.944S ;
04.233.946S ; 04.233.948S ; 04.233.917S ; 04.233.921S ; 04.233.925S ; 04.233.929S ;
04.233.931S ; 04.233.933S ; 04.233.935S ; 04.233.937S ; 04.233.939S ; 04.233.941S ;
04.233.943S ; 04.233.945S ; 04.233.947S ; 04.233.949S ;

Ø 10 mm

04.233.016S ; 04.233.020S ; 04.233.024S ; 04.233.028S ; 04.233.030S ; 04.233.032S ;
04.233.034S ; 04.233.036S ; 04.233.038S ; 04.233.040S ; 04.233.042S ; 04.233.044S ;
04.233.046S ; 04.233.048S ; 04.233.017S ; 04.233.021S ; 04.233.025S ; 04.233.029S ;
04.233.031S ; 04.233.033S ; 04.233.035S ; 04.233.037S ; 04.233.039S ; 04.233.041S ;
04.233.043S ; 04.233.045S ; 04.233.047S ; 04.233.049S ;

Ø 11 mm

04.233.116S ; 04.233.120S ; 04.233.124S ; 04.233.128S ; 04.233.130S ; 04.233.132S ;
04.233.134S ; 04.233.136S ; 04.233.138S ; 04.233.140S ; 04.233.142S ; 04.233.144S ;
04.233.146S ; 04.233.148S ; 04.233.117S ; 04.233.121S ; 04.233.125S ; 04.233.129S ;
04.233.131S ; 04.233.133S ; 04.233.135S ; 04.233.137S ; 04.233.139S ; 04.233.141S ;
04.233.143S ; 04.233.145S ; 04.233.147S ; 04.233.149S

Ø 12 mm

04.233.216S ; 04.233.220S ; 04.233.224S ; 04.233.228S ; 04.233.230S ; 04.233.232S ;
04.233.234S ; 04.233.236S ; 04.233.238S ; 04.233.240S ; 04.233.242S ; 04.233.244S ;
04.233.246S ; 04.233.248S ; 04.233.217S ; 04.233.221S ; 04.233.225S ; 04.233.229S ;
04.233.231S ; 04.233.233S ; 04.233.235S ; 04.233.237S ; 04.233.239S ; 04.233.241S ;
04.233.243S ; 04.233.245S ; 04.233.247S ; 04.233.249S

Ø 14 mm

04.233.428S ; 04.233.430S ; 04.233.432S ; 04.233.434S ; 04.233.436S ; 04.233.438S ;
04.233.440S ; 04.233.442S ; 04.233.444S ; 04.233.446S ; 04.233.448S

Endcap:

衛部醫器輸字第 036428 號

04.233.000S ; 04.233.005S ; 04.233.010S

Nut and Washers:

衛部醫器輸字第 036428 號

04.045.780S ; 04.045.781S ; 04.045.782S

以下為 113 年 10 月 31 日前本案特材收載之歷史資料

特材代碼：FBN05RFNA0S1

中文品名：“信迪思”進階型逆行股骨髓內釘系統

英文品名：“Synthes”RFN-Advanced Retrograde Femoral Nailing System (RFNA)

許可證字號：衛部醫器輸字第 036428 號

自 113 年 3 月 1 日生效，擴增產品型號

Screws:滅菌(Tube Packaging)

04.045.026TS ; 04.045.028TS ; 04.045.030TS ; 04.045.032TS ; 04.045.034TS ; 04.045.036TS ;
04.045.038TS ; 04.045.040TS ; 04.045.042TS ; 04.045.044TS ; 04.045.046TS ; 04.045.048TS ;
04.045.050TS ; 04.045.052TS ; 04.045.054TS ; 04.045.056TS ; 04.045.058TS ; 04.045.060TS ;
04.045.062TS ; 04.045.064TS ; 04.045.066TS ; 04.045.068TS ; 04.045.070TS ; 04.045.072TS ;
04.045.074TS ; 04.045.076TS ; 04.045.078TS ; 04.045.080TS ; 04.045.082TS ; 04.045.084TS ;
04.045.086TS ; 04.045.088TS ; 04.045.090TS ; 04.045.095TS ; 04.045.100TS ; 04.045.105TS ;
04.045.110TS ; 04.045.115TS ; 04.045.120TS

04.045.326TS ; 04.045.328TS ; 04.045.330TS ; 04.045.332TS ; 04.045.334TS ; 04.045.336TS ;
04.045.338TS ; 04.045.340TS ; 04.045.342TS ; 04.045.344TS ; 04.045.346TS ; 04.045.348TS ;
04.045.350TS ; 04.045.352TS ; 04.045.354TS ; 04.045.356TS ; 04.045.358TS ; 04.045.360TS ;
04.045.362TS ; 04.045.364TS ; 04.045.366TS ; 04.045.368TS ; 04.045.370TS ; 04.045.372TS ;
04.045.374TS ; 04.045.376TS ; 04.045.378TS ; 04.045.380TS ; 04.045.382TS ; 04.045.384TS ;
04.045.386TS ; 04.045.388TS ; 04.045.390TS ; 04.045.395TS ; 04.045.400TS ; 04.045.405TS ;
04.045.410TS ; 04.045.415TS ; 04.045.420TS

特材代碼：FBN05RFNA0S1

中文品名：“信迪思”進階型逆行股骨髓內釘系統

英文品名：“Synthes”RFN-Advanced Retrograde Femoral Nailing System (RFNA)

許可證字號：衛部醫器輸字第 036428 號

以下為 113 年 2 月 29 日前收載之產品型號

Nail:

Ø 9 mm

04.233.916S ; 04.233.920S ; 04.233.924S ; 04.233.928S ; 04.233.930S ; 04.233.932S ; 04.233.934S ;
04.233.936S ; 04.233.938S ; 04.233.940S ; 04.233.942S ; 04.233.944S ; 04.233.946S ; 04.233.948S ;
04.233.917S ; 04.233.921S ; 04.233.925S ; 04.233.929S ; 04.233.931S ; 04.233.933S ; 04.233.935S ;
04.233.937S ; 04.233.939S ; 04.233.941S ; 04.233.943S ; 04.233.945S ; 04.233.947S ; 04.233.949S ;

Ø 10 mm

04.233.016S ; 04.233.020S ; 04.233.024S ; 04.233.028S ; 04.233.030S ; 04.233.032S ; 04.233.034S ;
04.233.036S ; 04.233.038S ; 04.233.040S ; 04.233.042S ; 04.233.044S ; 04.233.046S ; 04.233.048S ;
04.233.017S ; 04.233.021S ; 04.233.025S ; 04.233.029S ; 04.233.031S ; 04.233.033S ; 04.233.035S ;
04.233.037S ; 04.233.039S ; 04.233.041S ; 04.233.043S ; 04.233.045S ; 04.233.047S ; 04.233.049S ;

Ø 11 mm

04.233.116S ; 04.233.120S ; 04.233.124S ; 04.233.128S ; 04.233.130S ; 04.233.132S ; 04.233.134S ;
04.233.136S ; 04.233.138S ; 04.233.140S ; 04.233.142S ; 04.233.144S ; 04.233.146S ; 04.233.148S ;
04.233.117S ; 04.233.121S ; 04.233.125S ; 04.233.129S ; 04.233.131S ; 04.233.133S ; 04.233.135S ;
04.233.137S ; 04.233.139S ; 04.233.141S ; 04.233.143S ; 04.233.145S ; 04.233.147S ; 04.233.149S

Ø 12 mm

04.233.216S ; 04.233.220S ; 04.233.224S ; 04.233.228S ; 04.233.230S ; 04.233.232S ; 04.233.234S ;
04.233.236S ; 04.233.238S ; 04.233.240S ; 04.233.242S ; 04.233.244S ; 04.233.246S ; 04.233.248S ;

04.233.217S ; 04.233.221S ; 04.233.225S ; 04.233.229S ; 04.233.231S ; 04.233.233S ; 04.233.235S ;
04.233.237S ; 04.233.239S ; 04.233.241S ; 04.233.243S ; 04.233.245S ; 04.233.247S ; 04.233.249S
Ø 14 mm
04.233.428S ; 04.233.430S ; 04.233.432S ; 04.233.434S ; 04.233.436S ; 04.233.438S ; 04.233.440S ;
04.233.442S ; 04.233.444S ; 04.233.446S ; 04.233.448S

Endcap: 04.233.000S ; 04.233.005S ; 04.233.010S

Nut and Washers: 04.045.780S ; 04.045.781S ; 04.045.782S

Screws:未滅菌

04.045.026 ; 04.045.028 ; 04.045.030 ; 04.045.032 ; 04.045.034 ; 04.045.036 ; 04.045.038 ;
04.045.040 ; 04.045.042 ; 04.045.044 ; 04.045.046 ; 04.045.048 ; 04.045.050 ; 04.045.052 ;
04.045.054 ; 04.045.056 ; 04.045.058 ; 04.045.060 ; 04.045.062 ; 04.045.064 ; 04.045.066 ;
04.045.068 ; 04.045.070 ; 04.045.072 ; 04.045.074 ; 04.045.076 ; 04.045.078 ; 04.045.080 ;
04.045.082 ; 04.045.084 ; 04.045.086 ; 04.045.088 ; 04.045.090 ; 04.045.095 ; 04.045.100 ;
04.045.105 ; 04.045.110 ; 04.045.115 ; 04.045.120 ; 04.045.326 ; 04.045.328 ; 04.045.330 ;
04.045.332 ; 04.045.334 ; 04.045.336 ; 04.045.338 ; 04.045.340 ; 04.045.342 ; 04.045.344 ;
04.045.346 ; 04.045.348 ; 04.045.350 ; 04.045.352 ; 04.045.354 ; 04.045.356 ; 04.045.358 ;
04.045.360 ; 04.045.362 ; 04.045.364 ; 04.045.366 ; 04.045.368 ; 04.045.370 ; 04.045.372 ;
04.045.374 ; 04.045.376 ; 04.045.378 ; 04.045.380 ; 04.045.382 ; 04.045.384 ; 04.045.386 ;
04.045.388 ; 04.045.390 ; 04.045.395 ; 04.045.400 ; 04.045.405 ; 04.045.410 ; 04.045.415 ;
04.045.420

滅菌

04.045.026S ; 04.045.028S ; 04.045.030S ; 04.045.032S ; 04.045.034S ; 04.045.036S ; 04.045.038S ;
04.045.040S ; 04.045.042S ; 04.045.044S ; 04.045.046S ; 04.045.048S ; 04.045.050S ; 04.045.052S ;
04.045.054S ; 04.045.056S ; 04.045.058S ; 04.045.060S ; 04.045.062S ; 04.045.064S ; 04.045.066S ;
04.045.068S ; 04.045.070S ; 04.045.072S ; 04.045.074S ; 04.045.076S ; 04.045.078S ; 04.045.080S ;
04.045.082S ; 04.045.084S ; 04.045.086S ; 04.045.088S ; 04.045.090S ; 04.045.095S ; 04.045.100S ;
04.045.105S ; 04.045.110S ; 04.045.115S ; 04.045.120S ; 04.045.326S ; 04.045.328S ; 04.045.330S ;
04.045.332S ; 04.045.334S ; 04.045.336S ; 04.045.338S ; 04.045.340S ; 04.045.342S ; 04.045.344S ;
04.045.346S ; 04.045.348S ; 04.045.350S ; 04.045.352S ; 04.045.354S ; 04.045.356S ; 04.045.358S ;
04.045.360S ; 04.045.362S ; 04.045.364S ; 04.045.366S ; 04.045.368S ; 04.045.370S ; 04.045.372S ;
04.045.374S ; 04.045.376S ; 04.045.378S ; 04.045.380S ; 04.045.382S ; 04.045.384S ; 04.045.386S ;
04.045.388S ; 04.045.390S ; 04.045.395S ; 04.045.400S ; 04.045.405S ; 04.045.410S ; 04.045.415S ;
04.045.420S